

Nicole Lavallee (SBN 165755)
Daniel E. Barenbaum (SBN 209261)
Jeffrey V. Rocha (SBN 304852)
BERMAN TABACCO
44 Montgomery Street, Suite 650
San Francisco, CA 94104
Telephone: (415) 433-3200
Facsimile: (415) 433-6382
Email: nlavallee@bermantabacco.com
dbarenbaum@bermantabacco.com
jrocha@bermantabacco.com

*Counsel for Lead Plaintiff Alameda County
Employees' Retirement Association
and Lead Counsel for the Class*

[Additional Counsel on Signature Page]

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

***Caption Consistent With Order Appointing
Lead Plaintiff dated April 22, 2020, ECF No. 49:***

ALAMEDA COUNTY EMPLOYEES'
RETIREMENT ASSOCIATION and
OKLAHOMA FIREFIGHTERS RETIREMENT
SYSTEM, Individually and on Behalf of All Others
Similarly Situated,

Plaintiffs,

v.

PORTOLA PHARMACEUTICALS, INC.; SCOTT
GARLAND; MARDI C. DIER; SHELDON
KOENIG; HOLLINGS C. RENTON; JEFFREY
W. BIRD; LAURA BREGE; DENNIS FENTON;
JOHN H. JOHNSON; DAVID C. STUMP;
H. WARD WOLFF; GOLDMAN SACHS & CO.
LLC; CITIGROUP GLOBAL MARKETS INC.;
COWEN AND COMPANY, LLC; WILLIAM
BLAIR & COMPANY, L.L.C.; and
OPPENHEIMER & CO. INC.,

Defendants.

No. 3:20-cv-00367-VC

**FIRST AMENDED
CONSOLIDATED COMPLAINT
FOR VIOLATION OF
SECURITIES LAWS**

CLASS ACTION

JURY TRIAL DEMANDED

Original Caption:

PAUL HAYDEN, Individually and on Behalf of
All Others Similarly Situated,

Plaintiff,

v.

PORTOLA PHARMACEUTICALS INC., SCOTT
GARLAND, and MARDI C. DIER,

Defendants.

JOHN R. MCCUTCHEON, Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

vs.

PORTOLA PHARMACEUTICALS INC., SCOTT
GARLAND, SHELDON KOENIG, and MARDI C.
DIER,

Defendants.

No. 3:20-cv-00949-VC

CLASS ACTION

SOUTHEASTERN PENNSYLVANIA
TRANSPORTATION AUTHORITY, on behalf of
itself and all others similarly
situated,

Plaintiff,

v.

PORTOLA PHARMACEUTICALS, INC., SCOTT
GARLAND, MARDI C. DIER, SHELDON
KOENIG, HOLLINGS C. RENTON, JEFFREY W.
BIRD, LAURA BREGE, DENNIS FENTON,
JOHN H. JOHNSON, DAVID C. STUMP, and H.
WARD WOLFF,

Defendants.

No. 3:20-cv-01501-VC

CLASS ACTION

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Court-appointed Lead Plaintiff the Alameda County Employees' Retirement Association ("Lead Plaintiff") brings claims individually and on behalf of investors who purchased or otherwise acquired common stock of Portola Pharmaceuticals, Inc. ("Portola" or the "Company"), including shares sold in the August 2019 Offering (defined below), between January 8, 2019 and February 26, 2020, inclusive (the "Class Period"), and were damaged as a result (the "Class").

Lead Plaintiff asserts claims under two federal statutes against Defendants. First, Lead Plaintiff brings claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a) (the "Exchange Act"), and the rules and regulations promulgated thereunder, including Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b5"). Second, Lead Plaintiff brings claims for violations of Sections 11, 12(a)(2), and 15 of the Securities Act of 1933, 15 U.S.C. §§ 77k, 77l(a)(2), and 77o (the "Securities Act"). The Securities Act claims allege strict liability and/or negligence and do not sound in fraud.

Lead Plaintiff alleges the following based upon personal knowledge as to the allegations specifically pertaining to Lead Plaintiff and upon information and belief as to all other matters. Lead Plaintiff's information and belief as to allegations concerning matters other than itself and its own acts are based upon an investigation of Lead Counsel, which included a review and analysis of (a) U.S. Securities and Exchange Commission ("SEC") filings by Portola; (b) press releases and other public statements; (c) securities analyst reports and media reports about the Company; and (d) interviews with former Portola employees who were employed by Portola before and/or during the Class Period, as well as customers/potential customers of Portola. Moreover, Lead Plaintiff believes that further substantial evidentiary support exists for these allegations, which will be revealed after a reasonable opportunity for discovery.

I. SUMMARY OF THE ACTION

1. Portola is the classic case of a company misleading the investing public regarding the actual market value of its main product—it was counting money it hoped to make before it actually made it. Few would argue that Portola’s Andexxa drug sounded—in a vacuum—good on paper: a drug with the potential to fill a void, save lives, and make money. Certainly, Portola screamed it from the rooftops. But context is king, and little context can be gleaned from within that vacuum. Portola went through money like it was water developing two coagulant drugs. One, Bevyxxa, failed before this story began, leaving all of Portola’s eggs in its Andexxa basket. Unfortunately, Andexxa did not translate from that vacuum into a product in demand in the real world.

2. While a company is entitled to obtain financial benefit from a drug it put significant resources into developing, obtaining such benefit requires that there be commensurate demand for the product and that it be utilized. The federal securities laws prohibit the company from lying to the investing public—the people who fund the company’s efforts—regarding the value of the drug and the market’s reception of it.

3. From a 30,000-foot view, Andexxa looked like a drug that had promise—one without an FDA-approved¹ competitor to combat significant bleeds caused by either of two anticoagulant drugs: Eliquis and Xarelto. From 30,000 feet, it looked almost like a fairytale. And, as it turns out, the story that Portola told about the marketing and sales of Andexxa was just that—a fairytale.

4. Closer to the ground and out of that vacuum, Andexxa’s survival was more fraught. First, while no FDA-approved competitor existed for Eliquis- and Xarelto-related

¹ “FDA” refers to the U.S. Food and Drug Administration.

serious bleeds, at least one—a 4-factor Prothrombin Complex Concentrate (“4F-PCC”) called Kcentra—did exist and was prescribed off-label regularly by doctors for years. Second, Kcentra cost just a fraction of what Andexxa cost. As one hospital Confidential Witness (or “CW”) (defined below) articulated, hospitals have treated life-threatening Xarelto- and Eliquis-related bleeding events without the need for Andexxa for the last six to seven years. According to a Portola salesperson Confidential Witness, even a professor of pharmacology paid by Portola to speak at a June 2018 conference spoke very favorably about Andexxa *from a clinical perspective*, but told the room full of hospital pharmacists that, *from his practical perspective*, he would never use Andexxa due to its cost and that he was going to use Kcentra instead.

5. When launching Andexxa in May 2018, Portola appeared to go out of its way to neutralize the impact of Kcentra as a competitor to Andexxa and did not identify it as a significant threat to its new wonder-drug. Dr. Stuart Connolly, Executive Committee Chairman of the original ANNEXA-4 study that supported Andexxa’s FDA approval on an accelerated basis, articulated that Kcentra should not be a viable competitor to Andexxa because “there’s no biological plausibility for why it will reverse a Factor Xa inhibitor.” And the then-CEO, William Lis, re-emphasized that point, stating, “[W]hat we know from the use of the other reversal agents, again, you have a drug called Kcentra, no biological plausibility. Evidence showing it does not reverse the activity.”

6. Putting its hands over its eyes did not serve Portola well, unfortunately. The disproportionately lower cost of Kcentra when compared to Andexxa was ***not attributed to how cheap*** Kcentra was, but rather ***how expensive Andexxa was***. As described by former employees of Portola, as well as actual and potential customers (*i.e.*, hospital pharmacies), Andexxa’s arrival in the marketplace was met with a tempered reaction. At costs between approximately

\$25,000 and \$50,000 per dose, depending on the severity of the bleed, Portola's Andexxa salesforce was met with what one former salesperson CW described as "shock." Another salesperson CW said that "[i]t was a struggle for me from day one to sell Andexxa" and "the hospital pharmacists were terrified of [Andexxa], and not from a clinical point; strictly from a cost point." Yet another salesperson CW said, "Many of us came onboard thinking that this was such an attractive product and a potential blockbuster. As soon as the customers saw the price, they said that they have lived without it for five or six years and that they could live without it longer." And a CW from a large hospital said that most of the hospitals in his/her hospital's peer group have made the same determination concerning Andexxa—that it is too costly when compared with other treatments.

7. As CWs describe it, hospitals acted warily toward Andexxa and the Portola salesforce right from the start of the Class Period. Many refused to purchase it. Others purchased it in limited quantities—*e.g.*, one, two, six doses—while at the same time restricting use to only the most dire life-threatening bleeds, such as cranial bleeds. No CWs described it being used on less severe bleeds, whether gastrointestinal- or cosmetic-surgery-related or other. A CW from a large hospital system that purchased Andexxa said that the system used it less than six (6) times in total.

8. What is remarkable about the story that the CWs weave together about hospital reaction to Andexxa is how uniformly their accounts fit the same narrative: (a) limited demand; and (2) limited utilization where purchased—either usage depth (amount) or breadth (types of bleeds). These limitations and barriers to successfully selling and fully commercializing Andexxa were, as reported by multiple salesperson and hospital CWs, consistent throughout the entire Class Period.

9. Portola and its management *cannot claim* that they did not know about this narrative—about sales demand and utilization; about cost as barrier to sales and revenue. On its own, it is absurd to suggest otherwise, where Andexxa was Portola’s only viable product and the Company’s complete success or utter failure rested on the Company’s ability to sell its product successfully. But irrespective of that, Defendant Scott Garland (“Garland”) admitted at the beginning of the Class Period to focusing on cash expenses as the Company’s “fuel,” given that its burn rate was high; he would not be focused on expenses without knowing about sales, demand, and utilization. Further, midway through the Class Period, he agreed with an analyst that said that the Company’s story was “Andexxa, Andexxa, Andexxa”—there was little else to look at. Finally, after the truth about Andexxa was revealed and Portola announced its fiscal year (“FY”) 2020 results on February 26, 2020, Defendant Garland doubled down on Andexxa’s revenue growth, saying he was “laser focused” on it.

10. There is other evidence of Defendants’ knowledge of the difficulty selling Andexxa due to cost, low demand, and underwhelming utilization. First, there were nationwide calls and meetings held at a San Francisco hotel near Portola’s headquarters organized by VP of Sales Randy St. Laurent (who reported to Defendant Sheldon Koenig (“Koenig”), who in turn reported to Defendant Garland). Salesperson CWs report that cost as a barrier to Andexxa sales was a discussion topic in some way at every sales meeting, both regionally and nationwide. Some report that Garland spoke on those calls and at those meetings, where he sidestepped the issue of cost and instead tried to push the value of the drug to hospitals. Ironically, that was not the medicine these salespeople needed, and one CW reports that those in Portola’s Sales Division felt that they did not get enough support from the “executive team” concerning the price of Andexxa. Second, salesperson CWs report that they used customer relationship management

(CRM) software and Excel spreadsheets to track meetings, sales, and utilization; they recorded what sort of limitations hospitals were imposing on use of the drug and how restrictive they were; and management had access to it and, they suggest, tracked it. Third, Defendants themselves conceded that they tracked key metrics, such as hospitals orders. Given these facts, it defies belief for Defendants to argue that they lacked information about their only product's sales, demand, and utilization. As one salesperson CW stated, with Portola being such a small company where everyone was connected, it would be impossible for the Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") to assert that they were unaware that sales of Andexxa were "nonexistent because of its egregious pricing."

11. Ultimately, Portola threatened some salespeople's jobs—two CWs report that they were told that they had to sell Andexxa to a particular hospital each or they would be terminated. One of those salespeople had been in the top quarter in terms of results the prior quarter.

12. Unfortunately, despite this clear customer reaction to the drug, Defendants provided a decidedly different narrative to investors and analysts, thereby artificially inflating the value of its stock.

- a. ***They touted demand.*** At the beginning of the Class Period in January 2019 and carrying through for a good part of the year, Portola and its executives were saying that demand was strong and growing and that "the current trajectory should continue at a linear rate." They repeated this mantra over and over again. And at a Morgan Stanley Global Healthcare Conference in September 2019, Portola CEO Garland said that it "feel[s] like there's a lot of momentum, wind in our sales for Portola...."

- b. ***They touted utilization***—depth and breadth. With regard to depth, even in August 2019, Mr. Garland said that “[t]here’s nothing that we’re seeing today that makes us concerned about a lack of pull-through or a plateauing of our utilization.” And with regard to breadth, in November 2019, one executive said on an analyst conference call that “Andexxa is being used in all ranges of bleeds.”
- c. ***They touted Andexxa’s ascension.*** Indeed, on August 7, 2019, Garland stated that based on information, “Andexxa is becoming the standard of care for patients on apixaban or rivaroxaban.”

13. To support these claims, the Company pointed to the reorder rate and hospital adds. Yet the Company never fully explained what made up the non-GAAP measure of “reorder rate” (they measured reorders since Andexxa’s public inception) and refused to share detailed numbers when pressed. On May 8, 2019, an analyst tried to get the new-versus-reorder metric for the prior quarter, and Defendant Koenig deflected, stating, “We haven’t done that [sic] we [don’t] want to be doing that on this call.” Ultimately, in or around November 2019, Portola disclaimed using that metric going forward.

14. It goes without saying that Defendants’ statements about demand and utilization were not mere corporate puffery. They are based on current, quantifiable, verifiable facts. And they are highly material—Portola’s publicly filed SEC Forms 10-K and 10-Q (defined below) from within and immediately preceding the Class Period are riddled with disclosures of the importance of demand, utilization, and hospitals’ decisions to buy and use Andexxa. Words have meaning. Defendants chose to speak about those important issues, and those statements affected investors who relied upon them.

15. While Portola commercially started to scale-up in January 2019 and log some new sales, at least one CW reports that by mid-year (a) some hospitals were stocking the Andexxa ordered but not-reordering and (b) sales people started to see evidence of larger returns.

16. Defendants were motivated to mislead the investing public because of the Company's cash needs. Throughout all of this, one thing that was top of mind for Portola was cash—the Company was burning through a lot and seeking more. Portola's launch of Andexxa via its limited Early Supply Program in Spring and Summer 2018 occurred just as the launch of its coagulant drug in the spotlight—Bevyxxa—failed. As one salesperson CW who had worked on the sale of Bevyxxa explained, the Bevyxxa rollout was a “disaster.” On August 13, 2018, after what a Credit Suisse analyst report referred to as a “stunningly slow ... launch” of Bevyxxa, *Bloomberg* reported that a Morgan Stanley analyst had stated that he was “worried about mgt.’s ability to fund the company” in light of disappointing second quarter (or “Q2”) sales. Commenting on the Company's burn rate of \$326 million in the previous year, 2018, Mr. Garland stated on a January 8, 2019 call to analysts, “Cash is our fuel on this journey. We take it very seriously. It's what it's going to take to get us from this side to the other side of the river or the pond, and we're being very judicious with how we spend our money.”

17. In line with that, on February 28, 2019, the Company entered into a credit agreement for a term loan of \$125.0 million to be advanced in two equal tranches of \$62.5 million each—the first, immediately. However, the second tranche was to be made available near year's end—on November 15, 2019—**and only if** conditions were met (a) regarding certain regulatory approvals as well as (b) that consolidated net sales for the three fiscal quarter periods ending September 30, 2019 were at least \$50.0 million. Defendants needed that cash infusion and used clever accounting to get there.

18. Further, and riding the wave of Defendants’ hype over 2019 about demand and utilization of Andexxa, in August 2019, eight months into the Class Period, Portola closed a secondary public offering (the “Offering,” defined below) of 8,035,715 shares of common stock at a price of \$28.00 per share (with an option for additional shares granted to the underwriters), for gross proceeds of approximately \$250 million for the Company.

19. As the inevitable day approached that the truth about Andexxa’s troubles would be discovered, Portola moved away from talking about reorder rates and miraculous growth and demand, and into pushing out new scientific data in an attempt to demonstrate the value of the drug. As one article published by *Seeking Alpha* on January 30, 2020 claimed after Andexxa’s problems came to light: “Portola has published numerous pieces of research during 2019 supporting management’s claim that Andexxa is a best-in-class solution for treatment of Factor Xa related bleeds. ... As I will describe below however, *doubts have been cast about these results that are quite troubling and could prevent Andexxa from making it onto hospital formulary lists.*”² Both salesperson and hospital CWs relay that this later data pushed out by Portola was met with skepticism—that from their perspectives it did not change minds.

20. Defendants’ public statements regarding the Company’s achievements and trajectory were untrue and misleading when made. And indeed, at the end of the Class Period, Defendants’ misrepresentations finally caught up with them. Much of the truth was revealed on January 9, 2020, when the Company announced its fourth quarter (or “Q4”) 2019 results and issued a press release stating that total net U.S. Andexxa revenue was projected to be \$24

² Edmund Ingham, *Portola: Doubtful Trials And Falling Sales Make Andexxa An Unlikely Blockbuster*, Seeking Alpha (Jan. 30, 2020), <https://seekingalpha.com/article/4320305-portola-doubtful-trials-and-falling-sales-make-andexxa-unlikely-blockbuster>.

million, down from \$33 million the prior quarter—a decline of 27%. Further information was provided in a follow-up analyst presentation on a January 14, 2020 industry conference put on by Portola in response to market and analyst reaction to the January 9 announcement and again on February 26, 2020 in a press release and analyst call.

21. On January 9 and January 14, 2020, the Company announced that three factors had impacted sales: (1) a “\$5 million gross to net adjustment due to a return reserve for short-dated product”; (2) “[f]lat quarter over quarter demand due to a decrease in utilization, primarily in tier 1 accounts”; and, added on January 14, 2020, (3) “lower distributor purchases to manage inventory” in order “to keep their inventory levels at a constant level in the fourth quarter.” This \$5 million “onetime” adjustment to account for short-dated product returns was significant as these returns effectively reduced net product revenues during the fourth quarter from approximately \$32 million to Portola’s reported \$28 million (a reduction of 18%).

22. These results, along with comments made concurrently, seemingly recognize what the CWs had known all along: that demand and utilization were weak, caused in part by decisions of hospital pharmacies to curtail purchasing and utilization and in part by the fact that distributors had retained or otherwise possessed excessive inventory.

23. Significantly, what these disclosures (and, in particular, those highlighting the return reserve) and the Company’s 2019 financial statements make clear is that Defendants made materially false and misleading statements throughout their financial reporting because they failed to comply with Generally Accepted Accounting Principles (or “GAAP”)—which they were required to follow and expressly stated in each filing that they were following—in

assessing potential returns and recognizing the underlying sales as revenue.³ Under GAAP and Accounting Standards Codification (“ASC”), Topic 606 (“ASC 606”), *Revenue from Contracts with Customers*, the Company lacked a reasonable basis, ***including relevant historical evidence***, to determine that ***“it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved”***⁴ (ASC 606-10-32-11)—a determination that was required for the Company to report net revenues. Andexxa was a new and novel drug, and the Company expressly disclosed that it had ***“limited commercial sales history on which to base its assumptions.”*** The Company also lacked any data from market-specific historical data because there were no comparable products on the market from a sales perspective.

24. Moreover the Company’s actions suggested that significant returns would be likely under the factors to be considered under ASC 606. The Company was selling short-shelf-life product (6-12 months) with a very generous right of return, which offset the risk of buying short-dated product, all while knowing that longer-shelf-life product was already manufactured and waiting in the wings to be sold. Additionally, the existence of a more cost-effective alternatives, such as Kcentra, raised significant uncertainty regarding the market acceptance of Andexxa, its expected sell-through, and product use assumptions. These uncertainties heightened the risk of return and raised significant hurdles for determining whether a significant reversal of revenue was probable of occurring. Under those circumstances, Portola should not have recognized revenue at the time of sale to the distributors because it could not reasonably

³ GAAP is a set of accounting principles recognized by the accounting profession and the SEC as the uniform rules, conventions, and procedures necessary to define accepted accounting practice at a particular time.

⁴ All emphasis is added, unless otherwise noted.

conclude that it was probable that a significant reversal in the amount of revenue would not occur. And indeed, the FY 2019 10-K demonstrates that the Company under-reserved for returns for product sold in 2018 by 48%.

25. Significantly, the Company effectively admitted that it was not following its own revenue recognition policy by reporting net revenue without calculating reserves every quarter. Throughout the Class Period, the Company represented that its accounting policy provided that it would net out the appropriate amount of reserves to provide a net revenue figure. However, with this January 2020 disclosure about its Q4 2019 results, the Company admitted that it had not properly netted out reserves throughout 2019. Specifically, when asked by an analyst whether the “\$5 million reserve is for product that is short-dated, but has not yet been returned,” CFO Mardi Dier (“Dier”) responded that the reserve addresses both

what’s been returned, *it’s a little bit of catch-up for the year*, and then you need to make an estimate of what you think may be returned based on what you’ve seen so far. That’s just accounting for return reserves. So we come up with a calculation. We feel good about the \$5 million, taking the \$5 million now. *And then moving forward, we’ll have our classic return reserve adjustment as part of our gross-to-net calculations.*

* * *

We do think this onetime adjustment takes in effect a little bit of what came back *during the year* and what may come back going forward with some short-dated products still outstanding. *But going forward, our reserves will be calculated into our gross to net on a more normalized basis.* And like I said, we’re already starting to shift the long-dated 36-month product. We started that in November. So we feel good about this one adjustment.

26. The Company’s improper recognition of revenue, failure to adequately reserve for product returns, and its shipment of Andexxa inventory to Portola’s distributors in excess of demand during the third quarter (or “Q3”) helped the Company exceed a \$50 million milestone which was critical to accessing \$62.5 million in seriously needed capital on November 15, 2019.

27. On the January 9, 2020 news and conference call, the Company's share price plummeted by \$9.98, or approximately 40%, to close at \$14.76 per share on January 10, 2020, on heavy trading volume. Analysts lowered expectations for the Company.

28. Portola used a prior-used investor-presentation template for the January 14, 2020 follow-up presentation on its Q4 2019 results. Glaringly absent from that updated deck—the slide that had been there all year claiming that “Andexxa Demand is Strong and Growing.” Indeed, the following slide was presented to investors on November 5, 2019 (only two months earlier):



29. Then on February 26, 2020, after the market closed, the Company revealed that the future of Andexxa was even more dire when it announced lower than expected FY 2019 losses and that the Company would have to restructure its operations to be “laser focused” on Andexxa by, among other things, shutting down the almost stagnant Bevyxxa (which had been focused on just ten hospitals more than a year before) and reorganizing the Andexxa operation. Portola further described a bleaker-than-expected future for Andexxa when it revealed that it

expected to add 350 new hospitals in 2020 (down from 425 hospital additions in 2019). As one analyst wrote of that news, “On tonight’s call, Portola indicated that it expects to add approximately 350 ... new hospital accounts during 2020, implying a *deceleration* from the 425 hospitals added in 2019.”

30. Portola, via Defendant Koenig, baldly tried to claim that drug utilization reviews / Pharmacy and Therapeutic (“P&T”) Committee reviews, conducted at hospitals to consider whether and how drugs should be included in their formularies, somehow curtailed revenue. But Defendants Koenig and Garland had already played that card at the launch of the commercialization effort at the outset of the Class Period, as did Koenig’s predecessor Jeet Mahal at the more limited prior launch in May 2018, suggesting at that time that the bulk of those reviews had been completed (or would be completed within a couple of months of launch).

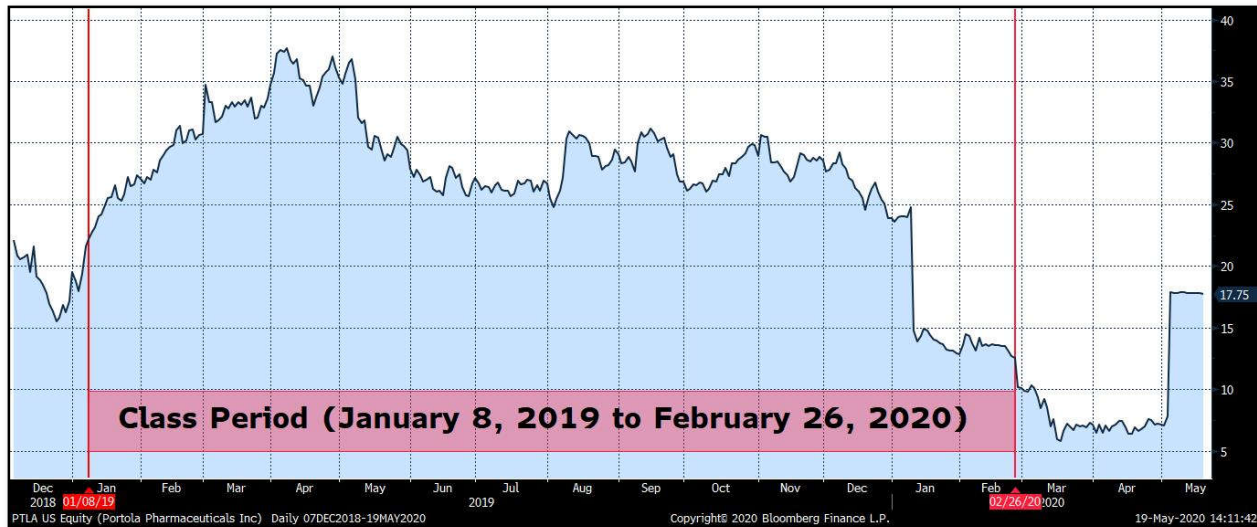
31. While at the launch of non-scaled-up Andexxa in May 2018, Portola had claimed that Kcentra was not a viable competitor (§82), it turns out that the Company knew otherwise. Only after the truth of its materially false and misleading statements came to light, in the Company’s 2019 SEC Form 10-K filed on February 28, 2020, the Company added disclosures that starkly highlighted just how precarious the initial medical study that supported the FDA’s approval of Andexxa in May 2018—ANDEXXA-4—was. Andexxa had been approved under the FDA’s Accelerated Approval process, which allows drugs to be approved substantially based on evidence of an effect on a biomarker endpoint that is considered reasonably likely to predict clinical benefit *rather than a clinical endpoint*. Andexxa’s FDA approval was based on the change from baseline in healthy volunteers only, rather than a randomized controlled trial which compares Andexxa to other types of care the enrolling institution would provide in the absence of Andexxa. And on February 28, 2020, in its filed FY 2019 Form 10-K, Portola admitted not

just that it had been encountering material difficulties in selling Andexxa in 2019 due to competition from “widely used” 4F-PCCs such as Kcentra, a scenario Portola had downplayed as at launch, but also that potential deficiencies in that initial study supporting the Accelerated Approval process, ANDEXXA-4:

[The] studies [relied upon for approval] have *inherent limitations* as compared with a randomized controlled trial. For example, *we do not have comparator arm data, including clinical head to head data against the treatment options which were used by hospitals prior to the availability of Andexxa, which we believe continue to be widely used, including off-label use of 4F-PCCs [e.g., Kcentra] and other coagulation factors. In addition, the efficacy statements in our product label are limited as the result of our single-arm, open-label study.* These limitations have a significant impact on our ability to market Andexxa ... [and] can also increase resistance to utilization by hospital formulary committees....

32. As news about the true status of the Andexxa was revealed, the stock price fell, closing at \$10.17 per share, a decline of \$2.35 per share (or 19%) on heavy trading volume on February 27, 2020. The following chart reflects the price of Portola’s stock from December 3, 2018 to May 18, 2020:⁵

⁵ On May 5, 2020, an announcement was made that Alexion Pharmaceuticals, Inc., a global biopharmaceutical company, would acquire Portola for \$18 per share in a cash deal worth approximately \$1.4 billion (the “Acquisition” or “Merger”). On that news, the stock jumped from a prior close of \$7.76 to \$17.85, and it has stayed consistently at or around that level until the Acquisition.



II. JURISDICTION AND VENUE

33. Lead Plaintiff's claims arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, and Sections 11, 12, and 15 of the Securities Act, 15 U.S.C. §§ 77k, 77l, and 77o.

34. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and Section 22 of the Securities Act, 15 U.S.C. § 77v. This Court has jurisdiction over Defendants because each Defendant has sufficient minimum contacts with this district, particularly since Portola's principal place of business is located in South San Francisco, California.

35. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act and Section 22 of the Securities Act because many of the false and misleading statements were made in or issued from this district. Many of Defendants' acts and practices that give rise to this complaint substantially occurred in this district.

36. In connection with the acts, conduct, and other wrongs Lead Plaintiff alleges, Defendants, directly and indirectly, used the means and instrumentalities of interstate commerce,

including, but not limited to, the United States mail, interstate telephone communications, and national securities markets.

III. INTRADISTRICT ASSIGNMENT

37. Pursuant to Northern District of California Civil Local Rules 3-2(c) and 3-5(b), assignment to the San Francisco Division of this district is proper because a substantial part of the events or omissions, which give rise to the claims asserted herein, occurred in San Mateo County, and Portola's principal place of business is located, in San Mateo County, California.

IV. THE PARTIES

A. Lead Plaintiff

38. On April 22, 2020, Alameda County Employees' Retirement Association ("ACERA") was appointed Lead Plaintiff. ECF No. 49. ACERA is a public pension fund that was established in 1947 and includes over 26,000 current and former public employees working in Alameda County, California who collectively invest their deferred wages to receive a secure income after retirement. As of December 31, 2019, ACERA managed approximately \$8.7 billion on behalf these public servants. As set forth in its Certification attached as **Exhibit 1**, ACERA purchased Portola common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

B. Additional Named Plaintiff

39. The Oklahoma Firefighters Pension and Retirement System ("Oklahoma Firefighters") is a public pension system established for the benefit of firefighters in the state of Oklahoma. Created in 1980, Oklahoma Firefighters holds more than \$2.8 billion in net assets for the benefit of more than 25,000 members and beneficiaries as of June 30, 2020. As set forth in its certification attached as **Exhibit 2**, Oklahoma Firefighters purchased Portola common stock during the Class Period, including shares issued pursuant to the August 2019

Offering, and was damaged as a result. Specifically, but not exclusively, Oklahoma Firefighters purchased 7,889 shares of Portola common stock on August 14, 2019 directly in the Offering at the Offering price of \$28.00 per share.

C. Defendants

1. The Company

40. Defendant Portola Pharmaceuticals, Inc. is incorporated under the laws of Delaware with its principal executive offices located in South San Francisco, California. The Company is the issuer of the common stock sold in the Offering. Portola's common stock trades on the NASDAQ exchange under the symbol "PTLA." As of February 20, 2020, the number of shares outstanding of Portola's common stock was 78,080,365.

2. Officer Defendants

41. Defendant Scott Garland ("Garland") is, and at all relevant times was, the CEO and President of the Company, as well as a Director of Portola. Throughout the Class Period, he issued false and misleading statements for which he is liable under the Exchange Act. In addition, Garland signed and certified the Company's Annual Report on Form 10-K ("Form 10-K") for the year ended December 31, 2018, filed with the SEC on March 1, 2019 (the "FY 2018 Form 10-K"), Quarterly Report on Form 10-Q ("Form 10-Q") for the period ended March 31, 2019, filed with the SEC on May 8, 2019 (the "Q1 2019 Form 10-Q"), Form 10-Q for the period ended June 30, 2019, filed with the SEC on August 7, 2019 (the "Q2 2019 Form 10-Q"), and Form 10-Q for the period ended September 30, 2019, filed with the SEC on November 5, 2019 (the "Q3 2019 Form 10-Q"). Garland signed the Registration Statement (as defined below at ¶265) and is therefore liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials (as defined below at ¶265).

42. Defendant Mardi C. Dier (“Dier”) is, and at all relevant times was, an Executive Vice President and the CFO of the Company. Throughout the Class Period, she issued false and misleading statements for which she is liable under the Exchange Act. In addition, Dier signed and certified the FY 2018 Form 10-K, Q1 2019 Form 10-Q, Q2 2019 Form 10-Q, and Q3 2019 Form 10-Q. Dier also signed the Registration Statement and is therefore liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials.

43. Defendant Sheldon Koenig (“Koenig”) is, and at all relevant times was, an Executive Vice President and the Chief Commercial Officer of the Company. Throughout the Class Period, he issued false and misleading statements for which he is liable under the Exchange Act.

44. Defendants Garland, Dier, and Koenig (collectively, the “Officer Defendants”), because of their positions within the Company, possessed the power and authority to control the contents of the Company’s reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market.

45. The Officer Defendants were provided with copies of the Company’s reports and press releases alleged herein to be materially misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material nonpublic information available to them, the Officer Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were thereby materially false and/or misleading. The Officer Defendants are liable for the false and/or misleading statements pleaded herein.

3. Director Defendants

46. Defendant Hollings C. Renton (“Renton”) has served as Chairman of Portola’s Board of Directors (“Board”) since March 2010. Renton signed the Registration Statement and is therefore liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials. During the Class Period, Renton was a member of the Nominating and Corporate Governance Committee and the Commercial Advisory Committee. He was also a member of the Compensation Committee until his resignation on September 18, 2019.

47. Defendant Jeffrey W. Bird (“Bird”) has served as a Director of Portola since November 2003. Bird signed the Registration Statement and is therefore liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials. During the Class Period, Bird was a member of the Audit Committee and the Research and Development Advisory Committee.

48. Defendant Laura Brege (“Brege”) has served as a Director of Portola since January 2015. Defendant Brege signed the Registration Statement and is therefore liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials. During the Class Period, Brege was a member of the Audit Committee and the Commercial Advisory Committee.

49. Defendant Dennis Fenton (“Fenton”) has served as a Director of Portola since February 2015. Fenton signed the Registration Statement and is therefore liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials. During the Class Period, Fenton was a member of the Compensation Committee and the Research and Development Advisory Committee.

50. Defendant John H. Johnson (“Johnson”) has served as a Director of Portola since March 2014. Johnson signed the Registration Statement and is therefore liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials. During the Class Period, Johnson was a member of the Compensation Committee, the Nominating and Corporate Governance Committee, and the Commercial Advisory Committee.

51. Defendant David C. Stump (“Stump”) has served as a Director of Portola since September 2015. Stump signed the Registration Statement and is therefore liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials. During the Class Period, Stump was a member of the Nominating and Corporate Governance Committee and the Research and Development Advisory Committee.

52. Defendant H. Ward Wolff (“Wolff”) has served as a Director of Portola since November 2007. Wolff signed the Registration Statement and is therefore liable under the Securities Act for the materially untrue and misleading statements and omissions in the Offering Materials. During the Class Period, Wolff was a member of the Audit Committee.

53. Defendants Garland, Renton, Bird, Brege, Fenton, Johnson, Stump, and Wolff are collectively referred to hereinafter as the “Director Defendants.” Each of the Director Defendants signed the Registration Statement. In addition, as Directors and/or executive officers of the Company, the Director Defendants participated in the solicitation and sale of Portola shares to investors in the Offering for their own benefit and the benefit of Portola. The Director Defendants, because of their positions within Portola, possessed the power and authority to control the contents of the Offering Materials.

4. Underwriter Defendants

54. Defendant Goldman Sachs & Co. LLC (“Goldman Sachs”) served as an underwriter in the Offering. Goldman Sachs is a New York limited liability company with its headquarters at 200 West Street, New York, NY 10282.

55. Defendant Citigroup Global Markets Inc. (“Citigroup”) served as an underwriter in the Offering. Citigroup is a New York corporation with its headquarters at 388 Greenwich Street, New York, NY 10013.

56. Defendant Cowen and Company, LLC (“Cowen”) served as an underwriter in the Offering. Cowen is a Delaware limited liability company with its headquarters at 599 Lexington Avenue, 20th Floor, New York, NY 10022.

57. Defendant William Blair & Company, L.L.C. (“William Blair”) served as an underwriter in the Offering. William Blair is a Delaware limited liability company with its headquarters at 222 West Adams Street, Chicago, IL 60606.

58. Defendant Oppenheimer & Co. Inc. (“Oppenheimer”) served as an underwriter in the Offering. Oppenheimer is a New York corporation with its headquarters at 85 Broad Street, New York, NY 10004.

59. Defendants Goldman Sachs, Citigroup, Cowen, William Blair, and Oppenheimer are collectively referred to as the “Underwriter Defendants.”

60. The Underwriter Defendants acted as the underwriters of the Offering by offering, selling, and distributing the Portola common stock offered to the investing public and purchased by Lead Plaintiff, Oklahoma Firefighters, and members of the Class.

61. The chart below sets forth the number of shares purchased by each Underwriter Defendant in the Offering:

Name	Number of shares
Goldman Sachs & Co. LLC	2,973,215
Citigroup Global Markets Inc.	2,330,358
Cowen and Company, LLC	1,767,857
William Blair & Company, L.L.C.	803,571
Oppenheimer & Co. Inc.	160,714
Total:	8,035,715

62. As the underwriters of the Offering, the Underwriter Defendants earned lucrative fees for their participation in the Offering.

63. Each of the Underwriter Defendants was obligated under the federal securities laws to conduct a reasonable investigation into the truthfulness and accuracy of the statements contained in or incorporated by reference into the Offering Materials. The Underwriter Defendants purported to conduct an adequate and reasonable investigation into the operations of the Company, an undertaking known as a “due diligence” investigation. During their due diligence, the Underwriter Defendants had continual access to confidential corporate information concerning the Company’s business, financial condition, products, plans, assets, and growth prospects. A reasonable investigation into the truthfulness and accuracy of the Offering Materials, including the statements incorporated by reference, would have revealed that the Offering Materials contained materially untrue and misleading statements and omissions, as alleged below. As alleged, none of the Underwriter Defendants made a reasonable investigation into the truthfulness and accuracy of the Offering Materials.

V. BACKGROUND AND SUBSTANTIVE ALLEGATIONS

A. Company's Background

64. For most of its existence, Portola has been focused on the research and development of drugs in the areas of thrombosis (clotting of the blood), other hematologic (blood) disorders, and inflammation. At the time of the Company's May 2013 initial public offering ("IPO"), the Company had two lead therapeutics that it was focused on researching and developing with a goal of commercialization. These two potential blockbuster drugs were Bevyxxa and Andexxa.

B. Burn Rate from Extensive Research, Development, and Commercialization Expenses

65. Portola generated significant operating losses researching and developing Bevyxxa and Andexxa. The Company financed its costly research and development operations primarily through sales of equity securities; collaborations (including loans from collaboration partners); and a royalty-based financing arrangement and sales of commercial and development rights to some of its "product candidates."⁶

66. After Bevyxxa was approved by the FDA in June 2017 and Andexxa was approved by the FDA (at a 100 mg dose)⁷ in May 2018, Portola's capital needs significantly increased because the Company had to establish and scale-up manufacturing capabilities and a sales, marketing, and distribution infrastructure to commercialize Bevyxxa and Andexxa in the U.S. and abroad, and to complete additional clinical studies. In 2017, Portola burned through

⁶ FY 2018 Form 10-K.

⁷ FDA Accelerated Approval Letter dated May 3, 2018, at 3, <https://www.fda.gov/media/113285/download>.

\$225 million for its operating activities.⁸ The Company's burn rate increased in 2018 when cash required for operating activities increased to \$326 million.⁹ As of December 31, 2018, the Company had \$317 million in cash, cash equivalents, and investments, and an accumulated deficit of \$1.5 billion.¹⁰

67. Because of the burn rate, Garland commented on a conference call on January 8, 2019 ("Jan. 8, 2019 Conference Call") that: "Cash is our fuel on this journey. We take it very seriously. It's what it's going to take to get us from this side to the other side of the river or the pond, and we're being very judicious with how we spend our money." At that time, Garland said that Portola had "been able to push [its] cash runway into the second quarter of 2020 and ... lowered our OpEx guidance for 2018. So it is now \$355 million to \$365 million, that was a \$35 million to \$65 million reduction in our OpEx."

68. On February 28, 2019, the Company entered into a credit agreement that provided for a term loan in an aggregate principal amount of up to \$125 million to be advanced in two tranches subject to certain performance-based milestones related to Andexxa (the "Secured Term Loan").¹¹ The first tranche, in the amount of \$62.5 million, was drawn down immediately. The second tranche of \$62.5 million was to be available as of November 15, 2019 only if (i) the Company had received all regulatory approval from the European Medicines Agency ("EMA") for Ondexxya,¹² and (ii) Andexxa's consolidated net sales

⁸ Portola's Form 10-K for the year ended December 31, 2017, filed with the SEC on March 1, 2018 (the "FY 2017 Form 10-K"), at 64.

⁹ FY 2018 Form 10-K, at 57.

¹⁰ *Id.* at 17, 56.

¹¹ FY 2018 Form 10-K, Ex. 10.46.

¹² Ondexxya is the brand name of Andexxa marketed in Europe.

reported in compliance with GAAP for the three fiscal-quarter periods ending September 30, 2019 were at least \$50.0 million. If the Company did not achieve both these milestones, it would not receive the remaining \$62.5 million. On April 26, 2019, Ondexxya received its approval satisfying the first condition.¹³ Then, on November 21, 2019, the Company announced that it had met the necessary \$50 million in sales requirement (having hit \$80.4 million Andexxa net product revenues in the nine months ended September 30, 2019)¹⁴ and had drawn down the entire \$62.5 million available from the second tranche.¹⁵

C. Background of Bevyxxa

1. Bevyxxa's FDA Approval in June 2017

69. A little over four years after its IPO, on June 23, 2017, Portola announced that Bevyxxa was approved by the FDA as the “the first and only anticoagulant” for hospital and extended duration prophylaxis of venous thromboembolism (“VTE”), a condition in which dangerous blood clots form in the leg, groin, or arm in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE.¹⁶ The Company stated that it expected to launch Bevyxxa between August and November 2017. *Id.* On this news, shares of Portola increased 48.7% to close at \$56.91 per share by June 26, 2017, on heavy volume.

¹³ Current Report on Form 8-K (“Form 8-K”), filed with the SEC on May 8, 2019, Ex. 99.1; FY 2018 Form 10-K, at 4.

¹⁴ Q3 2019 Form 10-Q, at F-9.

¹⁵ Form 8-K, filed with the SEC on Nov. 21, 2019.

¹⁶ Press Release, Portola, *U.S. FDA Approves Bevyxxa® (betrixaban) First and Only Anticoagulant for Hospital and Extended Duration Prevention of Venous Thromboembolism (VTE) in Acutely Ill Medical Patients* (June 23, 2017).

70. In a June 26, 2017 report, an analyst from William Blair noted that that the “approval of Bevyxxa by the FDA significantly transforms Portola as it becomes one of the few biotechnology companies with a wholly owned, approved drug targeting a multibillion-dollar market opportunity.” The analyst commented that Bevyxxa and Andexxa both had “blockbuster potential” and could “reach over \$1 billion in annual sales, providing the opportunity for significant share appreciation given the company’s current market cap of just over \$3 billion.” To support the costly commercial launch of Bevyxxa, the Company conducted a public offering of common stock in September 2017, raising approximately \$380 million.¹⁷

2. January 2018 Commercial Launch of Bevyxxa is a Failure

71. The commercial launch of Bevyxxa was a monumental failure. From the outset, the commercial launch was delayed until the first quarter (or “Q1”) of 2018 due to manufacturing issues. By March 1, 2018, shares of Portola had fallen back to \$31.56 per share. Bevyxxa’s sales of \$606,000 for the first quarter of 2018 were well-below expectations. Second quarter sales were even worse at a mere \$33,000.

72. On July 27, 2018, Bevyxxa was denied approval by the EMA. In response, Portola’s share price fell 7.51% to close at \$38.31, on heavy volume.

73. During an August 9, 2018 earnings call discussing second quarter Bevyxxa sales (“Aug. 9, 2018 Conference Call”), Portola admitted that its Bevyxxa commercialization efforts were not being well received by hospitals stating, “We are experiencing a bottleneck in getting Bevyxxa on to the hospital protocols and electronic order systems.” Also, in an August 9, 2018 report, an analyst from William Blair noted that the second quarter sales were “well

¹⁷ FY 2018 Form 10-K, at 58.

below our estimate of \$1.3 million.”¹⁸ And in an August 10, 2018 report, an analyst from Credit Suisse downgraded the Company due to Bevyxxa’s “stunningly slow ... launch.” Further, on August 13, 2018, *Bloomberg* reported that a Morgan Stanley analyst had stated that he was “worried about mgt.’s ability to fund the company” in light of disappointing second quarter sales.

74. By September 2018, a little more than a year after its FDA approval, Portola’s first “blockbuster” drug was dead in the water. During a September 12, 2018 Morgan Stanley Global Health Care Conference, the Company announced a new strategy significantly curtailing its efforts to commercialize Bevyxxa. Dier stated Portola would “narrow[] [its] effort on Bevyxxa” by “drilling down on 10 of the hospitals that are on formulary,” referred to as “Centers of Excellence.” An analyst from William Blair in a September 20, 2018 report stated that “investor expectations for Bevyxxa ha[d] been essentially removed” from Portola’s valuation. The Company then decided to place the Bevyxxa commercialization on the back-burner to focus on Andexxa.¹⁹

¹⁸ Bevyxxa generated a mere \$639,000 in revenues *over the first half* of 2018. See Portola’s Form 10-Q for the period ended June 30, 2018, filed with the SEC on August 9, 2018 (the “Q2 2018 Form 10-Q”), at 33. In the third quarter of 2018, Bevyxxa new product revenue was *negative*, losing \$552,000 during that quarter. See Portola’s Form 10-Q for the period ended September 30, 2018, filed with the SEC on November 7, 2018 (the “Q3 2018 Form 10-Q”), at 4. The Company attributed the loss to “an adjustment to Bevyxxa product revenue as we adjusted our gross to net revenue estimates during the quarter, particularly in response to anticipated *returns due to product expiry*.” *Id.*

¹⁹ In the first two quarters of 2019, Bevyxxa sales were \$77,000 and \$74,000. See Q1 2019 Form 10-Q, at 4, Q2 2019 Form 10-Q, at 4. By the third quarter, Bevyxxa sales were a mere \$17,000. See Q3 2019 Form 10-Q, at 4.

75. Fifteen months later, on February 26, 2020, Portola announced that it would incur a \$27.5 million charge to wind-down Bevyxxa operations.²⁰

D. Background of Andexxa

1. May 2018 FDA Approval of Andexxa (via the FDA Accelerated Approval Pathway)

76. On May 3, 2018, after the market closed, Portola revealed that its second lead drug, Andexxa, had received accelerated approval by the FDA as the “first and only antidote” “indicated for patients treated with rivaroxaban [(also known as Xarelto)] and apixaban [(also known as Eliquis)], when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.” In response to this news, shares of Portola traded up to close at \$42.44 per share on May 4, 2018 (up \$8.66 or 25.64%), on heavy volume.

77. Years prior, on February 26, 2015, Portola announced²¹ that Andexxa “has been granted orphan drug designation by the FDA’s Office of Orphan Products Development for reversing the anticoagulant effect of direct or indirect Factor Xa inhibitors in patients experiencing a serious uncontrolled bleeding event or who require urgent or emergent surgery.” Portola noted that “[t]he FDA’s Orphan Drug Designation program provides orphan status to drugs and biologics that are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that currently affect fewer than 200,000 people in the United States.” The factors that supported Andexxa’s orphan drug status

²⁰ Portola’s Form 10-K for the year ended December 31, 2019, filed with the SEC on February 28, 2020 (the “FY 2019 Form 10-K”), at 48.

²¹ Press Release, *Portola Pharmaceuticals Receives FDA Orphan Drug Designation for Andexanet Alfa, Its Breakthrough-Designated Factor Xa Inhibitor Antidote* (Feb. 26, 2015), <https://investors.portola.com/2015-02-26-Portola-Pharmaceuticals-Receives-FDA-Orphan-Drug-Designation-for-Andexanet-Alfa-Its-Breakthrough-Designated-Factor-Xa-Inhibitor-Antidote>.

were different from many other, more traditional orphan drugs. Those other drugs would tend to have discrete and identifiable patient populations, as well as readily identifiable populations of treaters. Many such drugs were out-patient (non-hospital) drugs and were not carried on the hospital pharmacy's budget, but instead were either covered by insurance or paid for by the patient. Andexxa, on the other hand, focused on a very small outlier subpopulation of patients at hospitals with severe complications to bleeding conditions that would often arise in emergency departments and operating rooms—neither the patient population nor the treaters were easily identifiable, and Andexxa was being sold to be used only in the event of a very unlikely occurrence.

78. In a May 4, 2018 report, a William Blair analyst commented that we “believe Andexxa has blockbuster potential given the millions of patients treated with Factor Xa inhibitors globally and the lack of an approved agent to reverse the anticoagulant when these patients experience life-threatening bleeding events.” In a follow up report issued on May 7, 2018, the William Blair analyst stated “Andexxa has blockbuster potential and [we] are raising our peak sales estimate to \$1.6 billion from \$1.2 billion.”

79. Andexxa was approved under the FDA's Accelerated Approval pathway. The Accelerated Approval regulations allow drugs that are being developed to treat an unmet medical need to be approved substantially based on evidence of an effect on a biomarker endpoint that is considered reasonably likely to predict clinical benefit rather than a clinical endpoint. Andexxa's FDA approval was based on the change from baseline in anti-Factor Xa activity in healthy volunteers rather than a randomized controlled trial which compares Andexxa to other types of care the enrolling institution would provide in the absence of Andexxa. The FDA conditioned

Andexxa's approval upon conducting a post-marketing randomized controlled trial of Andexxa. This clinical trial was initiated in early 2019 and is expected to run for four years.

80. While Andexxa is the only FDA-approved drug of its kind, older and cheaper alternative treatments existed to treat severe bleeds in patients taking anticoagulants. These include the off-label use of treatments designed to enhance coagulation including Fresh Frozen Plasma ("FFP"), 4F-PCCs, recombinant activated Factor VII ("rFVIIa"), Vitamin K, protamine, or whole blood.²² Moreover, other blood thinners besides apixaban and rivaroxaban are in use, the effects of which Andexxa does not reverse.

81. Prior to the availability of Andexxa, Kcentra (the brand name of 4F-PCCs)²³ and other coagulant factors were widely used for the same indications that Andexxa was approved for, *i.e.*, reversing the anticoagulant activity of rivaroxaban and apixaban.²⁴ Although Andexxa received FDA-approval in May 2018, as of 2020, Kcentra and other anticoagulants continue to be "widely used."²⁵ The approximate cost of Kcentra is \$5,000 compared to \$25,000 for a low dose of Andexxa and \$49,500 for a high dose of Andexxa.²⁶

82. Despite Kcentra's effectiveness with less cost, Portola did not publicly consider it as a viable threat to Andexxa's commercialization. Then-CEO William Lis described it as being

²² FY 2018 Form 10-K, at 7.

²³ Press Release, *Portola Pharmaceuticals Presents New In Vitro Data Demonstrating that Four-Factor Prothrombin Complex Concentrates (4F-PCCs) Had No Direct Effect on Inhibition of Thrombin Generation by Factor Xa Inhibitors* (July 8, 2019) (the "July 8, 2019 Press Release").

²⁴ FY 2019 Form 10-K, at 19.

²⁵ *Id.*

²⁶ Marina Haque, Michael Gratson, Jodi Woerle, Fitz Tavernier Jr., *Beginning to Understand the Cost-effectiveness of Andexxa*, Georgetown Medical Review (May 9, 2019), <https://gmr.scholasticahq.com/article/7777-beginning-to-understand-the-cost-effectiveness-of-andexxa>.

launched to meet an “unmet medical need,” and that its price “reflects its novel attributes as well as its orphan drug designation and the targeted population of high risk patients that will benefit from the use of Andexxa.”²⁷ Dr. Stuart Connolly, Executive Committee Chairman of the original ANNEXA-4 study and Professor at McMaster University, articulated that Kcentra should not be a viable competitor to Andexxa:

[R]emember there’s a drug called Kcentra, there’s no biological plausibility for why it will reverse a Factor Xa inhibitor. When you look at the data, it shows it doesn’t reverse a Factor Xa inhibitor. When you now look at the clinical data that’s been published, it shows that it doesn’t have an effect on intracranial bleeds and hemostatic efficacy, it’s not indicated for it.²⁸

And CEO Lis reiterated those points:

[W]hat we know from the use of the other reversal agents, again, you have a drug called Kcentra, no biological plausibility. Evidence showing it does not reverse the activity. Evidence showing it does not control hemostatic efficacy, right, at a cost of somewhere between \$8,000 and \$12,000 of block – of box warning for its use just in warfarin and it’s used pretty extensively outside of the ICH. So I do – we do not think demand is going to be the issue.²⁹

83. Instead of considering Kcentra and other treatments, Portola instead tried to justify the cost of Andexxa by focusing on what would otherwise be an extended hospital stay. Portola then-CEO William Lis stated: “Importantly, we are confident we can build a successful Andexxa franchise by targeting just a select sub-population of patients with the most severe life-threatening bleeds. These are patients that have a 30-day mortality rate of up to 40%. They have an average length of stay of 10 days or more. And the cost to treat these patients in the hospital exceeds \$100,000.”³⁰

²⁷ Transcript of Andexxa® FDA Approval Call (May 4, 2015).

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

84. This costly-hospital-stay narrative was still pressed a year and a half later, near the end of the Class Period: at Portola's shareholder meeting, dubbed "Investor Day," John Fanikos, Executive Director of Pharmacy at Brigham and Women's Hospital in Boston, spoke on behalf of Portola and Andexxa:

We follow every patient and because my job includes the finances, I typically pull all of the cost associated with the patient's care. And what you'll see in the graphic to the right is, yes, indeed, *one of the most expensive component of a patient encounter is the Andexanet, but what we've learned now is by using this drug early, we may be avoiding subsequent cost downstream* that are associated with hospital, length of stay, with surgical intervention, with procedural intervention and certainly nursing care. *So I think there is a value story that people need to understand that the cost of the drug is associated with benefits that you may see downstream.*³¹

2. Andexxa's Early Supply Program

85. Upon receiving FDA approval, in May 2018, the Company began a limited commercial launch, referred to as the Early Supply Program (or "ESP"), in the United States using limited quantities of the drug manufactured under the clinical-scale process, referred to as Generation 1 (or "Gen 1") supply. The Gen 1 supply shipped as a powder in 100 mg, single use vials. Before use, the powder would be reconstituted with sterile water. A low dose was 400 mg while a high dose was 800 mg.

86. The ESP was intended to focus on approximately 30 to 40 hospitals that were predominantly clinical-trial sites for Andexxa and a limited number of Level I trauma centers and comprehensive stroke centers. The hospitals in the ESP received Gen 1 Andexxa product directly from the Company. Andexxa's wholesale price ranged from \$25,000 to \$49,500 depending on dosage level. In a May 7, 2018 report, a William Blair analyst commented that the price was "noticeably above our expected range of \$15,000 to \$20,000 per patient."

³¹ Transcript of Investor Day Call (Nov. 14, 2015).

87. During an earnings call with investors on November 7, 2018 (“Nov. 7, 2018 Conference Call”), Garland commented on the significant strategic changes that had been made at Portola, shifting corporate resources from Bevyxxa to Andexxa. Garland stated that the “*top priority of Portola is Andexxa* ensuring the approval of the Gen-2 supply and a successful launch.”

3. Approval of Generation 2 Andexxa and Full Commercial Launch

88. On December 31, 2018, Portola announced in a press release that the FDA approved Portola’s Generation 2 (“Gen 2”) manufacturing process which provided commercial scale volume to support a global launch that could meet worldwide commercial demand over the next several years.³² In response to this news, shares of Portola were up \$2.43 per share (an increase of 14.22%) to close at \$19.52 on December 31, 2018, on heavy volume.

89. Prior to that, at the Morgan Stanley Global Health Care Conference held on September 12, 2018, Portola’s Jeet Mahal, VP of Commercial Sales (who preceded Defendant Koenig in that position and ran the Early Supply Program), talked about the P&T Committee review process and how long it would take to get Gen 2 product online at hospitals. “A little later this year [2018], now with the announcement about PDUFA date [December 31, 2018], the sales team will have some bandwidth to start talking to accounts that are outside of the ESP program. And one of the key messages we’re going to deliver is that PDUFA date is at the end of the year and we’re going to be able to go to the hospitals and just as you allude talk to those that are able to get the P&T process started ahead of that date or at least scheduled for the first P&T or second P&T Committee meeting post PDUFA date. A lot of times these take a few months to

³² According to the FDA Andexxa Approval Letter dated May 3, 2019, the FDA approved the Gen 2 product with a 24 month shelf life.

get that schedule in order. We don't have a number in terms of a strong percentage in terms of how does that break down, *but we do think that a substantial portion of the hospitals we can reach will be able to either get the P&T done ahead of time or schedule within a couple months of the PDUFA date.*"³³

90. Gen 2 Andexxa shipped in 200 mg/vials compared to 100 mg/vials for Gen 1 Andexxa sold during the ESP period. According to Garland in a May 8, 2019 conference call ("May 8, 2019 Conference Call"), Portola received "a lot of positive feedback on the 200 milligram/vial in terms of improving the constitution time.... And actually one of the reasons why we're seeing some of the Gen 1 hospitals transition over to Gen 2, because it's an easier reconstitution time it speeds up the door to needle time."

91. The full commercial launch of Andexxa was announced at the January 8, 2019 Conference Call with investors led by Garland who was purportedly brought on to Portola as CEO in September 2018 because of his prior experience with "multiple billion dollar product launches."³⁴ During the conference call discussing the commercial launch of Andexxa, Garland stated, "This is, by far, the most important destination for Portola and that is Andexxa. I tell folks internally all the time that *our first, second, third priority, fourth priority, fifth priority* are demonstrating that Andexxa can achieve the potential that we believe that it can achieve."

³³ Transcript of Morgan Stanley Global Health Care Conference Call (Sept. 12, 2018).

³⁴ Press Release, *Portola, Portola Pharmaceuticals Names Scott Garland President and Chief Executive Officer* (Sept. 20, 2018).

4. Change in Andexxa Distribution Model for Gen 2 Commercial Launch

92. The commercial launch of Gen 2 also resulted in a change in the Company's distribution model by selling to specialty distributors who would then fill Andexxa orders from hospitals. During the January 8, 2019 Conference Call, Dier announced:

We're moving from what we call a drop shipping method, which we would deliver the product directly to the hospital and now it will be through our distributors, through orders through distributors, and now we'll be going through our distributors so there will be some stocking going into first quarter. We're not going to say how much or what our estimate is, but maybe we'll give more of a sense of that on our Q4 call, or maybe down into our Q1 call, but it is important to know that, that is a change in how we'll recognize revenue. ***Everything will be recognized when we sell into the distributors.***

93. In its FY 2018 Form 10-K, the Company stated that it sells Andexxa to "specialty distributors and wholesalers in the United States ('Customers')." These Customers subsequently resell products to hospitals, pharmacies, and long-term care centers. The Company stated that it would "recognize revenue on product sales when the Customer obtains control of our product, which occurs at a point in time (upon delivery)." ***The Company did not report gross revenues, only revenues net of applicable reserves for variable consideration, including returns, discounts, and allowances.***

5. Addition of Consignment Sales to Business Model

94. Garland announced during the January 8, 2019 Conference Call that as part of the Gen 2 commercial launch, the Company started offering "consignment" sales. This was where Portola's Customers (their specialty distributors) offered hospitals the opportunity to stock Andexxa on their shelves without having to pay for it. The hospitals would pay a small percentage to keep the inventory on their shelves, so it gave that hospital the opportunity to have access to Andexxa without paying up front. The hospitals would pay when they used the product. Garland noted that consignment "is all handled by the wholesalers and it's something

they offer to customers.” According to Garland, “when [the Company] talk[ed] to pharmacists, they say that this is one of the most important offerings for them to be able to help the access and reimbursement environment.”

95. During the May 8, 2019 Conference Call, John Curnutte, Executive Vice President and Head of Research & Development commented that “if you look at how many institutions are using consignment again it’s, at this point it’s represents really a small portion of our overall sales.” During the August 7, 2019 conference call (“Aug. 7, 2019 Conference Call”), Koenig noted that “as we started the consignment earlier this year, and again this is something that allows hospitals and patients to have greater access just another way of having access to Andexxa. This is something that is really operationalized through our specialty distributors, it still represents a small portion of our business.” During a February 26, 2020 conference call (“Feb. 26, 2020 Conference Call”), Koenig stated that “[c]onsignment is something that I would say that everybody is aware of.”

6. Throughout the Class Period, in Public Filings, Portola Disclosed that Demand and Utilization Were Materially Important to the Company’s and Andexxa’s Success

96. Throughout the Class Period, in quarterly and annual public filings with the SEC, Portola disclosed that issues surrounding demand and/or utilization were materially important to both the Company’s and Andexxa’s success. In each filing, Portola made clear that failure to meet expected demand and/or broad utilization (where utilization is part of marketing and sales goals) could impact Company operations, Andexxa, and the shareholders.

97. For example, in the FY 2018 Form 10-K filed on March 1, 2019, under Part I, Item 1A, entitled “Risk Factors,” Portola warned as follows: “If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially

adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment.”³⁵

- a. Under Section 1 (“Risks Related To Our Financial Condition and Need for Additional Capital”), Portola identifies the following risks factors, among others things, that could affect operating results:
 - i. “the level of demand and market acceptance;” and
 - ii. “the timing, cost and level of investment in our marketing efforts to support sales.”³⁶
- b. Also under Section 1, Portola identifies the following risk factors, among others, that could affect financing requirements:
 - i. “product sales of Andexxa and, and if approved for commercial marketing, our product candidates;” and
 - ii. “the degree and rate of market acceptance of any products launched by us or partners.”³⁷
- c. Under Section 2 (“Risks Related to Commercial and Marketing Operations and the Development and Commercialization of Our Products and Product Candidates”), Portola states, “Our products may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success. [¶] Our success depends heavily on the launch and

³⁵ FY 2018 Form 10-K, at 17.

³⁶ FY 2018 Form 10-K, at 18.

³⁷ FY 2018 Form 10-K, at 19.

commercialization of our products. The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost-effective and safe.” Portola then identifies the following risk factors, among others, that could affect the degree of market acceptance:

- i. “the willingness of physicians and healthcare organizations to change their current treatment practices;”
- ii. “the willingness of hospitals and hospital systems to include our products as treatment options;”
- iii. “the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;” and
- iv. “the willingness of the target patient population to pay for our products, including co-pays under their health coverage plans.”³⁸

d. Under Section 7 (“Risks Related To Ownership Of Our Common Stock”), Portola identifies the following risk factors, among others, that could affect the market price for the Company’s common stock:

- i. “the timing and amount of revenues generated from sale of our products or product candidates;” and
- ii. “our ability to meet the expectations of investors related to the commercialization of our products and product candidates.”³⁹

³⁸ FY 2018 Form 10-K, at 21.

³⁹ FY 2018 Form 10-K, at 40-41.

98. As another example, in the Q3 2019 Form 10-Q for the quarter ending September 30, 2019, filed on November 5, 2019, under Part II, Item 1A, entitled “Risk Factors,” Portola warned as follows: “If any of the following risks actually materializes, our operating results, future prospects, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment.”⁴⁰

- a. Under Section 1 (“Risks Related To Our Financial Condition and Need for Additional Capital”), Portola identifies the following risks factors, among others things, that could affect operating results:
 - i. “the level of demand and market acceptance;” and
 - ii. “the timing, cost and level of investment in our marketing efforts to support sales.”⁴¹
- b. Also under Section 1, Portola identifies the following risk factors, among others, that could affect financing requirements:
 - i. “product sales of Andexxa and [its international version] Ondexxya, and if approved for commercial marketing, our product candidates;” and
 - ii. “the degree and rate of market acceptance of any products launched by us or partners.”⁴²

⁴⁰ 3Q 2019 Form 10-Q, at 9.

⁴¹ 3Q 2019 Form 10-Q, at 9-10.

⁴² 3Q 2019 Form 10-Q, at 11.

- c. Under Section 2 (“Risks Related to Commercial and Marketing Operations and the Development and Commercialization of Our Products and Product Candidates”), Portola states, “Our products may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success. [¶] Our success depends heavily on the launch and commercialization of our products. The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost-effective and safe.” Portola then identifies the following risk factors, among others, that could affect the degree of market acceptance:
- i. “the willingness of physicians and healthcare organizations to change their current treatment practices;”
 - ii. “the willingness of hospitals and hospital systems to include our products as treatment options;”
 - iii. “the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;” and
 - iv. “the willingness of the target patient population to pay for our products, including co-pays under their health coverage plans.”⁴³

⁴³ 3Q 2019 Form 10-Q, at 12-13.

d. Under Section 7 (“Risks Related To Ownership Of Our Common Stock”), Portola identifies the following risk factors, among others, that could affect the market price for the Company’s common stock:

- i. “the timing and amount of revenues generated from sale of our products or product candidates;” and
- ii. “our ability to meet the expectations of investors related to the commercialization of our products and product candidates.”⁴⁴

99. All of Portola’s public SEC filings during the class period (and immediately before) contain identical or similar disclosures of risk factors relating to demand and/or utilization.

7. Portola’s Formal Return Policy

100. Portola’s formal return policy, effective January 1, 2019, provided, *inter alia*:

Returnable Products

Product returns will be accepted from direct (specialty distributor) and non-direct (specialty distributor’s customers i.e., hospitals, clinics and pharmacies) accounts under the following conditions:

- Product returned within three (3) months prior to and six (6) months past expiration date
- Product in its original, unopened vial and bearing its original label

* * *

Expired Product

Portola will issue a credit for your return, please contact Portola Customer Service at (866) 916-0571 to obtain a return authorization.

* * *

⁴⁴ 3Q 2019 Form 10-Q, at 30.

Spoiled Product

The Andexxa® Replacement Credit Program provides for replacement credit of vials which are prescribed and prepared for a labeled indication, yet not administered because the patient has expired/coded or refused treatment, subject to certain limitations and conditions set forth by Portola.

* * *

Additional Information

- Portola will process credits through the distributor
- All products returned, including unauthorized returns, will be destroyed
- Returns for reasons related to product quality (for example, solution is cloudy, etc.) will continue to be processed by Portola. Please contact Portola's Quality Department at (866) 777-5947, Option 4. Product Complaints.

E. Detailed Confidential Witness Accounts

101. Accounts of thirteen (13) confidential witnesses (“CW”) contribute to the allegations of this complaint—seven (7) from former Portola salespeople and six (6) from customer and potential-customer hospital representatives. They vary geographically, from regions around the United States.

102. Remarkably, the stories from both customers’ and sellers’ perspectives each individually show that what they know about the key issues complained about herein are at odds with what Portola was communicating publicly—that Portola claimed strong, rising demand and an incredible reorder rate; and that Portola reported utilization that was both broad (types of bleeds) and deep (how often used). But what is more remarkable is how consistent each of their accounts are with the others in telling a story of what was actually happening, and how different a story that was from the one that Defendants were telling publicly. Their accounts help demonstrate that Portola’s representations and omissions were materially false and misleading.

103. Together, they paint a picture that suggests the following:

- a. Portola's pricing of Andexxa—magnitudes higher than its quasi-competitor, Kcentra (which is viewed by most hospitals as a form of alternative)—was the primary impediment to selling the product. In a vacuum, some saw Andexxa as being useful. But at the price offered, as compared to other available treatments, it was mainly rejected for purchase and addition to hospital formularies, or it was added gingerly (for example just two or three doses purchased that were then heavily restricted to only life-threatening traumatic bleeds that met a series of criteria and, in at least one instance, required the additional sign-off of two designated chief medical professionals).
- b. No one—whether salespeople, hospital clients, or potential clients—spoke to the concept of broad utilization of Andexxa beyond life-threatening traumatic cranial hemorrhaging. No formulary known to or described by these witnesses used Andexxa for any broader applications, such as serious gastrointestinal (or “GI”) bleeds, not to mention bleeds during elective surgeries or those less severe. To the extent hospitals purchased Andexxa at all, they did so for the most dire situations. One hospital CW said that the drug has been used across his/her large hospital system less than half a dozen times since his/her system started using it. Two hospital CWs said that severe restrictions to just those types of catastrophic bleeds that are life threatening are what they understand had been put in place in hospitals that had decided to use Andexxa.

- c. But more often, CWs suggest that hospitals were not purchasing the drug. That is certainly the message from salespeople CWs—that they regularly got significant push-back on pricing. Salespeople report hearing from hospitals that the price of Andexxa was shocking. Most hospitals would not purchase the drug. For some, despite trying to sell Andexxa day-in and day-out, they sold it to just one, two, or a handful of hospitals. As one seasoned CW salesperson put it, Andexxa was an “extremely tough sell.” And a hospital CW from a very large hospital that did not purchase Andexxa, said that most of the hospitals in his/her hospital’s peer group had made the same determination concerning Andexxa—that it is too costly when compared with other treatments.
- d. The CWs routinely described cost as an enormous barrier to selling Andexxa—a problem that plagued sales efforts regularly and consistently *throughout the entire Class Period*. Similarly, the CWs paint a picture of sluggish demand for Andexxa *throughout the Class Period*, with its shocking cost together with the availability of a feasible alternative such as Kcentra forcing hospital pharmacies to turn salespeople away without a sale (or with an extremely limited one). Nothing from the picture painted by the CWs’ consistent narratives suggests that demand had been booming until something changed in Q4 2019 to stop it. None describe the release of the October 2019 article as causing a seismic change in sales, nor do they tell a story of a sudden uptick in the P&T Committee reviews.

Rather, demand (and cost as a barrier to sales) and utilization was an ongoing problem throughout the Class Period.

- e. CWs state, in general terms, that Portola was aware that cost was the primary deterrent to selling the drug. Salespeople used CRM software and/or tracking spreadsheets to report not just purchases and reorders, but also whether the drug was broadly utilized or heavily restricted by hospitals to only severe life-threatening bleeds. Salespeople describe the cost-as-barrier issue being discussed at Portola meetings regularly. Some report having raised it with their managers as well. As one witness described, it was inconceivable that the most senior executives were not aware of this. There were quarterly national meetings that are reported to have included senior management, if not the CEO and CFO directly. Several CWs report hearing directly from Defendant Garland on both national sales calls and at national sales meetings, where he sidestepped the cost-as-barrier-to-sale issue and instead reiterated the value that he and Portola claimed, without wavering, should entice hospitals to purchase Andexxa at the exorbitant cost they claimed was merited.
- f. Some salespeople CWs describe discussing the cost-as-barrier issue with their managers. One manager responded that the price could not come down because it would affect the stock price and “venture capital.” Another responded by saying that the price will not change. A third said that Portola did not change its marketing strategy after hearing repeatedly about the issue. In fact, at least two witnesses explained that they were

“threatened” with being fired in Spring or Summer 2019 if they did not sell either a certain amount or ensure that a certain hospital was using the drug in the coming months. One of those CWs had just previously been ranked in the top quarter of Portola’s salespeople. That CW was ultimately fired when s/he could not deliver a particular hospital, and the other resigned upon being told that his/her job was in jeopardy. The corporate environment was described as “toxic” and “stressful.” A CW that was an employee in a support position at Portola’s corporate headquarters reports that people in the Sales Division did not feel like they were getting support from the Executive Management Team with regard to cost as a barrier to sales, and that many in that group were distrustful of Garland.

- g. The CWs knew that hospitals generally were either not buying Andexxa or purchasing very limited amounts—one or a few doses—and restricting the drug’s usage to just the most life-threatening bleeds (such as intercranial bleeds). The salespeople CWs knew this from their own experiences trying to (and almost always failing) to sell the drug, but also from Portola sales meetings (including those Company-wide or regional meetings where these issues were discussed) and general meetings. The hospital CWs knew this from their own experiences at the hospital or system pharmacies that were the decision-makers about whether to buy the drug and add it to their formularies and how to restrict its usage, but also from

keeping abreast about what other hospitals and systems in their industry were doing.

- h. At least two hospital CWs mentioned data supporting Andexxa's launch and sales process, and they question both its strength and limited nature (with one of them describing it as "flimsy"). One also questioned the results of a study that Portola conducted on Andexxa that were presented in December 2019, claiming that they were weak and did nothing to convince his/her hospital system to lift the stringent restrictions on Andexxa that were in place. (A salesperson CW also said that, from his/her perspective, the study did nothing to change opinions on Andexxa.) CWs also frame the decision-making issue as being between, for example, buying three doses of the drug on the one hand versus hiring someone to work a hospital on the other. That seems particularly true for rural hospitals, where resources and budgets are scarcer.
- i. CWs—both salespeople and hospital representatives—note the challenge of selling the drug when there is another remedy—Kcentra—at a significantly cheaper price. The general sense is that, while in a vacuum they may not be equal, (a) Kcentra has been used for years off-label to treat bleeds caused by the anticoagulants Xarelto and Eliquis, (b) the cost of Andexxa did not justify requiring use of Andexxa (and to the extent a hospital felt it did, then only for the most severe bleeds), and (c) the data supporting Andexxa was not that strong.

j. Errant CW comments also point to shelving of purchased Andexxa at the hospital or other warehousing, which forecasts impending lack of demand. For example, CW5 notes that some hospitals were stocking up but did little reordering. CW6 reports that s/he heard from salespeople s/he knew that “a lot of ... large health systems ... were returning Andexxa,” and that was well-prior to Q4 2019. And CW12, an employee in a support position at Portola’s San Francisco headquarters, reports that in the Spring of 2019, s/he heard from some in the Sales Division that sales had “come down.”

104. Together, none of these witnesses support the picture of ongoing or rising demand painted by Defendants during the Class Period. None suggest that there was broad or deep utilization of the drug, but rather that, to the extent a hospital purchased one or a few doses, it was used just for the most severe life-threatening bleeds. None suggest scenarios where the reorder rate was increasing, or even high. To the contrary, the CWs paint a picture where it was hard to fathom that these issues with demand and reserves were not visible and present quarter upon quarter.

Confidential Witness No. 1

105. CW1 was a Thrombosis Area Manager for Portola focusing on a major metropolitan area in New England from September 2018 through November 2019.

106. CW1 recounted that, from his/her perspective, hospitals had difficulty justifying the cost (\$25,000 for a low dosage and \$50,000 for a high one), that they believed that they had been getting along without a drug like Andexxa for many years and could still do so without spending so much. CW1 said that the data on the effectiveness of Andexxa was not supportive

enough to justify the cost versus the potential benefit. CW1 said s/he believes that some hospitals carry Andexxa to have it on hand as a “CYA,” but do not intend to use it.

107. CW1 explained that because Andexxa is so expensive, one hospital that s/he covered had in place very restrictive use protocols for the drug. According to CW1, that hospital would only allow Andexxa to be used for life-threatening intracranial bleeding. Andexxa was not on the hospital formulary for any other indication. As recounted by CW1, there were several layers of approval to get through before Andexxa could be administered. First, the hospital’s prescribing software required that the pharmacist scroll through a series of indications to ensure that they are met prior to authorizing use of Andexxa. Second, the hospital required the approval of both the attending neurosurgeon and the trauma specialist before Andexxa was authorized for use. CW1 reported that if both did not sign off, Andexxa would not be administered.

108. CW1 said that Portola management “100%” knew that high cost versus benefit is why hospitals don’t use Andexxa and that the few hospitals that carry Andexxa place restrictions on its use. According to CW1, Portola’s internal sales reporting program tracks this information. CW1 explained that sales reps are required to enter certain information into the system such as the name of the hospital, when the hospital was contacted, whether and when the P&T Committee is meeting about Andexxa, and, if Andexxa was purchased, what restrictions the hospital placed on prescribing Andexxa. CW1 said that Portola management knew that Andexxa is not widely used even by hospitals that carry it.

109. CW1 reported that, nonetheless, there was a lot of pressure to make sales of Andexxa. CW1 described the work environment to be “stressful” and “toxic.” CW1 reports that although s/he had been in the top quarter of performers earlier in 2019, CW1 was told in an April 2019 meeting with CW1’s regional manager that if a particular one of his/her hospitals did not

use Andexxa at least twice by November 2019, s/he would be let go. According to CW1, that hospital did not use any Andexxa during that period and in November s/he was terminated.

110. CW1 said that Portola attempted to address the cost versus benefit problem by conducting a new study and presenting additional data on Andexxa's effectiveness on other bleeding conditions. CW1 said that s/he did not believe that data changed anyone's opinion of the drug. Further, CW1 reported that, given all the restrictions on usage of Andexxa imposed by hospitals that purchased it, s/he would not say that the drug was broadly utilized. Rather, those hospitals that carry Andexxa restrict its use and others simply refuse to carry it because it is too costly.

111. CW1 said that even though s/he left in November 2019, s/he knew that sales of Andexxa had stalled. CW1 noted that, while sales did grow during the year s/he was with Portola, s/he believes that the restrictions on Andexxa's usage by hospitals hinders reorders.

112. CW1 explains that while s/he is not familiar with the specifics of Andexxa's return policy, CW1 understands that it is very generous. According to CW1, Andexxa could be returned and exchanged for new vials 6 months before the expiration date. CW1 further reported that the policy allowed for the return of Andexxa even if it was opened and mixed and prepared for use but not ultimately used. In that situation, CW1 thought that the hospital might get something like a 90% credit towards a new package.

113. CW1 also noted that the way that Andexxa was packaged led to some "waste"—that a package contained 4 vials, but at times dosing could require the use of 4½ or 5 vials. (CW1 did say that if the unused vials were not opened, they could still be used.)

Confidential Witness No. 2

114. CW2 was employed as a Regional Sales Manager for Portola focusing on an area in the Far West region of the United States from June 2017 through August 2018. CW2 said that s/he left Portola approximately 2 to 3 weeks before the launch of Andexxa, but did participate in the Company's training program to market the drug.

115. CW2 reported that there was tremendous pressure on the salesforce to sell Andexxa and that they were all instructed to use every contact they had and to advocate to get hospitals to stock Andexxa.

116. Like CW1, CW2 reported that sales representatives were threatened with losing their jobs if they did not get hospitals to stock the drug.

Confidential Witness No. 3

117. CW3 was an Area Thrombosis Manager at Portola focusing on an area in the Southwest region of the United States between 2018 and February 2019. CW3 said s/he was responsible for marketing and sales of Andexxa for the entirety of his/her Southwestern state.

118. Despite believing Andexxa to be an effective drug, CW3 identified Andexxa's price as being problematic. CW3 noted, "It was a struggle for me from day one to sell Andexxa." CW3 made clear that sales of Andexxa were stagnant throughout his/her time at Portola selling the drug. CW3 reported that Portola had two pricing levels for Andexxa: \$25,000 and \$50,000 per dose.

119. There were approximately 150 hospitals in CW3's state. S/he concentrated on hospitals with reported bleeding events. Yet during his/her tenure at Portola, CW3 was able to sell and get Andexxa stocked at just six hospitals. When asked, CW3 indicated that s/he had push-back from the hospitals from day one due to the high price of Andexxa. S/he later noted

that “the hospital pharmacists were terrified of [Andexxa], and not from a clinical point; strictly from a cost point.”

120. CW3 maintained that because Portola priced the drug very aggressively, it made it difficult for some hospitals to purchase. CW3 indicated that many of the hospitals that s/he called on were small rural hospitals. CW3 and the hospitals that s/he called on believed that Andexxa was “way too aggressively” priced. According to CW3, many could not afford Andexxa. CW3 said that because of the high cost, a hospital with 100 beds or less would have to make a choice between purchasing Andexxa and hiring a staff member. CW3 said, at another point, that the cost of using Andexxa just three times was the equivalent of hiring a new hospital staff member for these hospitals.

121. CW3 stated that the only hospitals that reordered Andexxa were huge hospitals. CW3 sold Andexxa to the largest health system in his/her region and they told him/her that they were going to restrict the use of Andexxa to their two flagship hospitals. Smaller hospitals in CW3’s state were not buying Andexxa and patients in those hospitals that would appear to benefit specifically from Andexxa were “life-flighted” to the appropriate facility that had Andexxa on stock.

122. CW3 said that the drug Kcentra was another anticoagulant reversal drug and is priced between \$7,000 and \$8,000 per dose. CW3 said that this is a cheaper alternative than Andexxa for many hospitals.

123. In fact, CW3 hosted a speaker event in June 2018 for the Hospital Pharmacy Society. The event was attended by 55 hospital pharmacists. Portola paid an honorarium to a noted professor of pharmacology and clinical specialist to speak about the benefits of Andexxa. During this speaking event, the speaker spoke very favorably about Andexxa from a clinical

perspective. At the end of his presentation, however, he told the room full of hospital pharmacists that he would never use Andexxa because it cost too much and that “I am going to use Kcentra.”

124. CW3 said that during a “one on one” meeting with his/her boss, an Area Business Director, they discussed the high cost of Andexxa and that the price of the drug was prohibitive. CW3 said s/he suggested that the Company should consider lowering the price. According to CW3, the Area Business Director’s response was that the Company could not lower the price because it would cause the stock price to go down and drive away venture capital.

Confidential Witness No. 4

125. CW4 was a Thrombosis Area Manager at Portola focusing on an area in Great Lakes region of the United States from February 2019 through the end of the Class Period. CW4 said that s/he joined Portola after the FDA approved production of the 200 mg dosage of Andexxa (Gen 2).

126. CW4 said s/he was only able to sell Andexxa to one hospital while with Portola. CW4 explained that the price of Andexxa was a shock to people. CW4 reported that the cost was a shock to many pharmacy directors, and it was the reasons for slow sales. CW4 said that the drug was anticipated for a few years and was believed to effective. But when Andexxa was compared to the price of Kcentra, pharmacists were shocked at the price difference.

127. CW4 reports that sales of Andexxa were slow throughout the time that s/he worked at Portola and sold Andexxa. During his/her time at Portola, s/he sold a total of 20-25 boxes of Andexxa, almost exclusively—if not exclusively—to a single account. Despite cost being an issue, CW4 reports that s/he participated in Portola national sales calls, which s/he

described as “rah rah” sessions. CW4 also reports attending a companywide national sales meeting in San Francisco.

128. Despite the difficulty with sales due to the cost of the drug, CW4 reports that s/he competed with two other salespeople also based in his/her state who overlapped with his/her sales area. CW4 covered a major metropolitan area and its immediate suburbs. There were 12 to 15 hospitals in his/her sales area, but s/he only called on 5 or 6. While two directly competed with him/her, there were seven salespeople in his/her state.

129. CW4 reported that sometime in 2019, an article was written by three pharmacists that provided hospital pharmacy directors with information to push back on ordering Andexxa.⁴⁵ Prior to this, CW4 believed hospitals were worried about being sued if a patient died following a severe bleed and it did not carry Andexxa. According to CW4, this article provided information many used to question carrying Andexxa at such a high cost. CW4 further stated that following the publication of this article, hospitals began to conduct their own Drug Usage Evaluation and many determined Andexxa was too expensive to carry when a cheaper alternative such as Kcentra was available.

130. CW4 states that s/he believed that Portola’s management was aware of how the article was being used against Andexxa, but they did not change Portola’s marketing strategy or consider lowering the price. CW4 said that the Company’s sales force always pushed to lower the price but was told the price is the price. CW4 did discuss the price issue with his/her supervisor.

⁴⁵ CW4 appears to be referencing Harry Peled, Nhu Quyen Dau & Helen Lau, *Key Points to Consider When Evaluating Andexxa for Formulary Addition*, Neurocritical Care (Oct. 22, 2019), <https://link.springer.com/article/10.1007/s12028-019-00866-6>.

131. CW4 said that the high cost of Andexxa put a strain on pharmacy budgets. CW4 explained that Andexxa—classified by the FDA as an “orphan” drug—was an inpatient drug that was paid for by the hospital. By contrast, orphan drugs generally are administered as outpatient drugs, the cost of which are often absorbed in part by third parties. CW4 reported that because Andexxa was an in-patient drug that comes out of the hospital pharmacy’s budget, it caused hospitals to put strict procedures in place for when and how to allow the drug’s use.

132. According to CW4, Andexxa was utilized for severe bleeds resulting from Xarelto or Eliquis and had to be administered within 18 hours of the event. CW4 explained that even though many patients receive Xarelto and Eliquis, Andexxa was an orphan drug because of the limitations on its use and the minimal off-label indications. CW4 said that it was this limited number of possible patients that allowed Andexxa to be classified as an orphan drug. CW4 explained that in this way Andexxa was different from other orphan drugs: with others, one is generally aware of the number of patients with the rare indications (and, presumably, which specialist treats them).

133. CW4 reports that s/he was not familiar with Portola’s return policy, but that s/he believed that the policy allowed for return of partially used doses if the patient had died before it was used. CW4 describes the return policy as basically an exchange policy.

Confidential Witness No. 5

134. CW5 was employed as a Thrombosis Area Manager for Portola focusing on an area in the Great Lakes region of the United States from February 2019 through March 2020. CW5 said that s/he was responsible for sales of Andexxa within a particular state and reported to the Regional Business Director.

135. CW5 stated that sales areas were determined by Zip Code. CW5 had no recollection of how many hospitals were in his/her region, but s/he said that s/he would have focused on Tier 1 hospitals. While s/he does not recall how many hospitals s/he approached, s/he ultimately had six (6) accounts that s/he covered.

136. According to CW5, Andexxa was a “niche” drug. CW5 said the indications for Andexxa are limited only to life-threatening bleeds for patients being treated with Eliquis or Xarelto; although many patients are treated with these drugs, few have life-threatening bleeds.

137. CW5 said Andexxa was very expensive. CW5 said that, from his/her perspective, the Portola sales force frequently advised management that the cost of the drug was hindering sales. According to CW5, the response from management was that the price was not going to be reduced. CW5 reported that those sales of Andexxa were not increasing in 2019. Based on his/her own observations and discussions with sales reps, CW5 reported that the rate of sales were not increasing during 2019. CW5 further reported that while the sales numbers were steady, some hospitals were stocking up but did little reordering.

138. In line with statements by CW3 and CW4, CW5 said that the biggest issues Portola had concerning Andexxa usage was the cost of the drug combined with the off-label use of Kcentra.

139. Implying that pharmacies were making the purchasing decisions, similar to statements made by or implications raised by CW3 and CW4, CW5 said that doctors liked Andexxa but were often told by pharmacy directors that it was not available or that its use was restricted and that Kcentra was the only available treatment on the formulary. CW5 said that pharmacy directors at many hospitals have the power to override a doctor’s order. CW5 said that

“all” of his/her accounts placed restrictions on the use of Andexxa due to its cost (and not due to the effectiveness of the drug).

140. CW5 reported that the Company knew that cost was hindering sales. For example, CW5 “always” informed his/her Regional Business Director of the issue. CW5 said that upper management understood that cost was impacting sales and causing restrictions to be put in place. There were national sales calls organized by the Vice President of Sales, Randy St. Laurent (who reported directly to Defendant Koenig) and that Defendant Garland spoke at some. CW5 says that during these calls, cost as the cause of slow sales and the implementation of restrictions was “always” discussed. When Garland addressed the issue, he would articulate value of the drug over the issue with cost.

141. CW5 also reported that there was a national sales meeting held in San Francisco. CW5 recalls that Defendant Garland spoke there, who again articulated value over cost. VP of Sales Randy St. Laurent also spoke there.

142. CW5 said that hospitals did not order Andexxa based on the number of patients treated with Eliquis or Xarelto, but on an estimate of usage. CW5 believes that hospitals made a cost versus utilization analysis and determined that it was too costly to stock more than 3 to 5 boxes of Andexxa or to reorder additional boxes given that the indications were so limited.

143. CW5 said that insurance coverage does not affect a hospital pharmacy department’s decision about whether to purchase Andexxa. CW5 explained that the expense for carrying Andexxa comes out of the pharmacy budget, but the reimbursement from Centers for Medicare and Medicaid Services (“CMS”) or another third party tends to go back to the general hospital accounts (*i.e.*, that the reimbursement may not get returned to the pharmacy’s budget).

(CW5 reported that s/he believes that the CMS had authorized between 50% and 65% cost reimbursement for Andexxa.)

144. CW5 stated that Portola has a very liberal return policy. CW5 explained that facilities could exchange Andexxa under three conditions. First, a hospital could return the dosage if it had expired. Second, a hospital could return the dosage if the patient for whom it was intended had passed away. And third, a hospital could return Andexxa if they had originally purchased the low-dose form of Andexxa (100 mg) (originally approved by the FDA) and wanted the higher dose (200 mg) after the FDA approved the manufacturing of it.

145. CW5 explained that the return policy was a way to mitigate risk for smaller hospitals that took on Andexxa with short shelf-life. Some of CW5's smaller hospital accounts had expressed concern about the short shelf-life. According to CW5, many hospitals that originally ordered the 100 mg dosage returned them to Portola for the larger dosage.

146. CW5 heard from other sales reps that beginning in the second half of 2019, there was an increase in the volume of returns, which s/he described as a large amount of returns of Andexxa.

Confidential Witness No. 6

147. CW6 was a Thrombosis Area Manager at Portola focusing on an area in the Rocky Mountain region of the United States from July 2017 until January 2019. His/her territory consisted of a state in that region, and s/he was the only sales rep responsible for that state. S/he was initially responsible for selling Portola's Bevyxxa and then Andexxa.

148. CW6 stated that s/he was working at Portola when Andexxa was originally launched. Prior to the launch of Andexxa, the Company was very quiet about how they intended to price the drug. When s/he asked about the expected pricing of Andexxa during his/her

interview, CW6 was told that the Company was not allowed to share pricing with him/her. S/he noted that s/he took the job “blind,” adding: “Many of us came onboard thinking that this was such an attractive product and a potential blockbuster. As soon as the customers saw the price, they said that they have lived without it for five or six years and that they could live without it longer.”

149. When the pricing was finally announced, CW6 reports that s/he and the other reps were “shocked” at how expensively the drug was priced. CW6 says that when Portola announced that they were going to sell Andexxa for between \$25,000 to \$50,000, there was shock and disbelief—at first from the sales reps, and then from the hospitals that they called on. CW6 said that s/he called on approximately 40 hospitals, and that 90% responded with a “flat-out ‘no.’”

150. CW6 says that s/he sold the drug to two Level I trauma centers with large bed capacity in his/her district. Yet, CW6 says, these trauma centers pushed back on the pricing of Andexxa and restricted the drug’s use.

151. CW6 noted that having two large accounts purchasing Andexxa was more than what the other sales reps were able to achieve. Many other hospitals refused to add Andexxa to their formularies because of its high price. These hospitals told CW6 that they have learned to manage bleeding with these patients, and they have strategies that have been working—that if Andexxa was priced differently, they would add it to their formularies. S/he added that Andexxa was an “extremely tough sell.”

152. CW6 stated that there were issues trying to sell Andexxa throughout the time s/he was doing so until s/he left. S/he reported that when it first launched, Andexxa was almost

impossible to sell due to its shockingly high price. Feedback from potential customers throughout that entire time was not positive. Most hospitals pushed back on price.

153. CW6 stated that management knew about the difficulty the price was causing salespeople. First, CW6 explained that sales information was tracked through CRM software provided by Salesforce. CW6 explained that all management had access to it and, based on his/her experience in the industry, they “absolutely” tracked sales number daily, if not hourly.

154. Second, CW6 indicated that the high price of Andexxa was “absolutely” discussed at sales meetings. S/he commented, “There wasn’t one single meeting where this was not discussed.” CW6 stated that Portola was such a small company and that everyone was connected, so it would be impossible for the CEO and CFO to assert that they were unaware that sales of Andexxa were “nonexistent because of its egregious pricing.”

155. CW6 stated that s/he attended four sales meetings a year, some district meetings and some national meetings. These meetings were generally held in a hotel in San Francisco near Portola’s headquarters. The executives at these meetings always asked, “Where is our take? What are the customers saying? What are the issues?” S/he indicated that everyone knew what the feedback was from the customers. CW6 explained that there were open discussions about issues, particularly the cost. S/he and other sales reps had discussions with managers, and s/he believes that the managers shared those concerns with the executive management. During breakout sessions by region, cost was a big concern. CW6 reported that sales reps were asked “what we were hearing [about cost] and how did we respond to the customers.”

156. CW6 recalled reporting to management at the end of 2018 that hospitals balked at the high price of Andexxa. S/he had started selling Andexxa in May 2018 and had been part of a separate sales group and visited clients between May and June 2018. The feedback that his/her

group had received from the hospitals was that Andexxa was too expensive. S/he then attended two meetings at the end of 2018 where the Company wanted the feedback from these hospitals and reasons for why Andexxa was not on their formulary. It was at that point that CW6 responded as reported.

157. CW6 stated that s/he understands that Portola was “absolutely” struggling to sell Andexxa in the period leading up to its August 2019 Offering. S/he noted that s/he started speaking to customers about Andexxa in May 2018.

158. CW6 reports that Andexxa clients were told that if their order was fulfilled, they may receive some short-dated product. S/he did not believe that Portola discounted the short-dated product. CW6 stated that Portola offered to replenish any short-dated product that was not used within the specified shelf life.

159. CW6 reports that s/he did not have a lot of returns in his/her territory. S/he left in January 2019 [which was soon after the ESP program ended and just as broader commercialization was starting up]. However, s/he heard about returns accelerating after s/he left Portola; s/he heard from “a lot of people across the country that there were large health systems that were returning Andexxa.” These returns happened before Q4 2019.

160. Prior to selling Andexxa, CW6 was first tasked with selling Portola’s predecessor drug Bevyxxa, an oral anticoagulant. S/he stated that Bevyxxa was approved by the FDA for venous thrombosis prevention. However, according to CW6, the rollout of Bevyxxa was a “disaster.” CW6 indicated that Portola should never have launched Bevyxxa based on the data that they had at the time. S/he noted that it was a great molecule that had very little data to support it. S/he explained that Bevyxxa had just one study which did not meet its primary endpoint, yet the product was still FDA approved. The data was good enough that the FDA

thought that there was an “unmet clinical need.” CW6 reported that even sites (presumably ones that s/he was working with) that had done the trials and had put the product in formulary never ordered it. S/he added: “It was a disaster and a terrible launch. It was a storm right before the Andexxa launch.”

Confidential Witness No. 7

161. CW7 is the Clinical Specialist Formulary Management and Drug Information Coordinator at a healthcare system in the Southeast region of the United States. CW7 has been in this position since October 2018.

162. CW7 said that s/he was the individual that brought Andexxa to the system. CW7 said that in October 2018, s/he presented Andexxa to the P&T Committee and it was added to the hospital system formulary. CW7 noted that while the data presented in the clinical trial was “flimsy,” it was felt that it was irresponsible to not carry the drug while prescribing Xarelto or Eliquis. The data was “flimsy” because the study lacked the use of a placebo. CW7 reported that s/he does not believe that Andexxa is ineffective, but only appropriate for certain indications. It is not a “miracle drug.”

163. CW7 said that the system has restricted the use of Andexxa to only life-threatening intercranial bleeding for patients being treated with Xarelto or Eliquis. It is CW7’s understanding that this is consistent with how hospitals throughout the country are utilizing Andexxa.

164. According to CW7, this decision was based on the clinical study data published in the New England Journal of Medicine. CW7 said that although the cost of Andexxa was high, it was not the reason for the restrictions. The restrictions were based on the data concerning Andexxa’s effectiveness. CW7 said that while Andexxa is an effective treatment, it is not a cure

for the causes of the bleeding event. CW7 reports that Andexxa has a short half-life of 1 hour (the time a drug's presence in the body to be reduced by 50%) and is only effective for 3 hours—that Andexxa provided a “drug holiday” for Xarelto and Eliquis by pausing their effects.

However:

- a. CW7 reports that after the dosage of Andexxa leaves the patient's system 3 hours later, the anticoagulation re-starts.
- b. CW7 also said that this time period should be enough for clotting to take place.
- c. CW7 further noted that if clotting had not occurred, it is not known if “redosing” with Andexxa is indicated. There is no data on that.

165. CW7 said that it is not good for the patient, the hospital, or society to spend \$50,000 for a treatment that would not alter the outcome of the patient's condition. CW7 stated that it is not always popular to make decisions about whether to carry a drug based on cost, but it is necessary. Medication costs are always involved in decision-making for formularies, where hospitals operate on a 2% profit margin, making cost important. If the medication was a “slam dunk” and always worked, it would be on the formulary. But with Andexxa, the clinical data showed that Kcentra was as effective in treating GI bleeding, and it was cheaper. If Andexxa had been cheaper, it would have gotten more usage.

166. CW7 said that the system only stocks one high dose and one low dose of Andexxa because the usage is so limited. CW7 said that the hospital system only authorizes Andexxa's use for intercranial bleeding, which is normally accompanied by a stroke. These events have high mortality rates even if the bleeding is stopped. According to CW7, doctors might not use Andexxa in every situation where it is indicated. CW7 said that if treatment with Andexxa

would not ultimately save the patient's life, it would probably not be used. CW7 also said that a doctor is more likely to use Andexxa on an otherwise young and healthy patient where the outcome is more certain.

167. In line with comments by CW3, CW4, and CW5 about hospitals using the less costly Kcentra in place of Andexxa, CW7 noted that the data on the use of Kcentra indicated it was as effective in many of the same situations as Andexxa.

168. CW7 said that s/he believes Portola is aware of how hospitals are using Andexxa. According to CW7, s/he has told the Portola sales reps covering the system what restrictions the hospital system put in place on Andexxa. CW7 said Portola salespeople would try to advocate for getting the restrictions expanded to include other indications, such GI bleeding.

169. CW7 attributed the early rise of Andexxa sales to hospitals "stocking up" on the drug. CW7 suggested that the drop in sales occurred because hospitals strictly limit the use of Andexxa and do not reorder.

Confidential Witness No. 8

170. CW8 is the Team Leader, Ambulatory Care, Emergency Department, and a member of the cardiology team for a large regional healthcare system in the Southeast region of the United States. CW8, with a PharmD degree, specializes in anticoagulation and investigational drug studies.

171. CW8 said that for at least the last 6 to 7 years since the anticoagulants Xarelto and Eliquis have been available, hospitals have treated life-threatening bleeding events without the need for Andexxa. CW8 said that his/her hospital system has Andexxa on its formulary but restricts its usage to only life-threatening events involving intercranial bleeding. CW8 said that throughout the entire hospital system, Andexxa had been used less than half a dozen times.

172. CW8 said that Andexxa does not stop the cause of the bleeding, but only binds or pauses the anticoagulant. The underlying cause of the bleeding is not affected, and when the binding wears off, the bleeding can restart.

173. CW8 said that the decision to restrict Andexxa's use is based on the cost versus benefit and the data presented in Portola's clinical trials. According to CW8, the data supporting use of Andexxa for GI bleeding was not enough to support its use for this indication.

174. Discussing the use of other treatments in place of Andexxa, CW8 said that the cost of Andexxa—\$20,000 to \$50,000, depending on the dosage—is a factor when evaluating cost versus benefit. CW8 explained that treatments such as Kcentra and Feiba⁴⁶ have been used in the past and have been shown to be effective for less cost. CW8 said that the cost of Andexxa was not the only factor, however, and that the past treatment and clinical data supported using the other treatments. CW8 explained the cost would prohibit using Andexxa for a routine application such as during elective surgery or to stop a nosebleed. CW8 noted that, in light of some of those factors (and having previously noted that the data did not support use for GI bleeds), s/he would say that Andexxa was not broadly utilized. CW8 stated that s/he believes that most hospitals have similar restrictions on Andexxa.

175. CW8 said Portola was aware that hospitals were restricting the use of Andexxa. According to CW8, Portola conducted an additional study of Andexxa. CW8 said that the results of the study were presented at the American Society of Hospital Pharmacists convention in

⁴⁶ Feiba is an activated prothrombin complex concentrate ("aPCC") which has been used for the same indications as Andexxa. It costs around \$5,000. See Marina Haque, Michael Gratson, Jodi Woerle, Fitz Tavernier Jr., *Beginning to Understand the Cost-effectiveness of Andexxa*, Georgetown Medical Review (May 9, 2019), <https://gmr.scholasticahq.com/article/7777-beginning-to-understand-the-cost-effectiveness-of-andexxa>.

December 2019 in Las Vegas, Nevada. CW8 said that, in his/her opinion, the study was weak and still not convincing enough to change the Andexxa restrictions.

176. CW8 said that in March 2020, during the virtual conference of the American College of Cardiology, s/he told the Portola representatives that the hospital system would continue to restrict Andexxa use and would not authorize it use for other types of indications such as GI bleeding.

177. CW8 said that while s/he does not have much information on Portola's return policy for Andexxa, s/he believes that it is generous and that returns may be allowed 30 days prior the expiration date.

Confidential Witness No. 9

178. CW9 is currently the Director of Pharmacy (and was previously the Assistant Director of Pharmacy) at a large hospital in the Great Lakes region of the United States since April 2013.

179. CW9 said that his/her team determined that the cost of Andexxa was too high when the benefits are compared with other medications. CW9 said that other PCC treatments such as Kcentra and Feiba are effective for significantly less cost. CW9 said that the cost versus benefit analysis was the only reason Andexxa is not on his/her hospital's formulary. CW9 said that there are no issues with the effectiveness of Andexxa; rather, it was determined to be too costly to carry when compared with other treatments.

180. CW9 said that s/he knows that his/her team communicated the cost issue directly to officials at Portola. CW9 said that it was his/her opinion that Portola knows that the issue with Andexxa is cost, and not efficacy.

181. CW9 explained that most hospitals in his/her hospital's peer group have made the same determination concerning Andexxa—that it is too costly when compared with other treatments. Although s/he does not work in a small rural hospital or area, CW9 stated that s/he believes that Andexxa is carried by smaller and rural hospitals.

182. CW9 noted that it is possible that, by carrying Andexxa, a hospital pharmacy may be unable to hire a technician or otherwise fill a vacant position.

183. CW9 explained that Andexxa is a drug that would come out of the hospital pharmacy's budget, and that third-party reimbursements do not affect the cost to the pharmacy department. CW9 explained that this is because Andexxa is an inpatient diagnostic-related group, or "DRG," medication. CW9 said that s/he thought, but was not sure, that the CMS had approved a New Technology Add-On Payment ("NTAP") for Andexxa, but s/he did not know how much it was. CW9 said that the NTAP would not have changed the cost versus benefit determination for his/her hospital.

Confidential Witness No. 10

184. CW10 has been the Director of Pharmacy Services at a regional hospital in the Southeast region of the United States since January 2019.

185. CW10 reports that the hospital's Chief Clinical Officer ("CCO") was tasked with approving the inclusion of any drug over a certain cost on his/her hospital's formulary.

186. CW10 stated that s/he was familiar with Andexxa and explained that it was indicated for the reversal of anticoagulation and was generally used in rare circumstances due to life-threatening or uncontrolled bleeding. A proposal was made to add it his/her hospital's formulary, but it was denied by the hospital's CCO.

187. CW10 reported that the emergency room (“ER”) physician group reviewed the formulary in January 2019 and asked for 5 drugs to be added to it, including Andexxa. The group’s proposal was to have at least a couple of doses of Andexxa on hand in the ER.

188. CW10 stated that all the drugs on the ER physician group’s list were approved except for Andexxa. CW10 said that the CCO told the group that the cost of Andexxa was too prohibitive to carry. S/he added that the CCO had said that there was no justification for Andexxa’s pricing when they could try other things.

189. CW10 reported that the CCO told the ER physician group that if they had a patient that was critical and needed Andexxa, then the patient should be immediately transferred by ambulance to a larger hospital within the area that carried Andexxa. CW10 said that the CCO further said that other drugs that were cheaper than Andexxa could be used, such as Kcentra.

Confidential Witness No. 11

190. CW11 has been the Director of Pharmacy Services at a metropolitan hospital in the Southeast region of the United States since 2003.

191. CW11 stated that the reason Andexxa was kept off the hospital’s formulary was its high cost. The hospital found a cheaper, reasonable alternative in Feiba.

192. CW11 stated that Andexxa went through a complete P&T Committee review sometime in 2018. S/he stated that, in addition to the P&T Committee review, the medical staff also agreed with the decision to select Feiba over Andexxa because of cost.

193. CW11 stated that s/he believes that many other hospitals in his/her state made a similar choice as his/her facility.

194. CW11 believes that Portola knew that the cost of Andexxa was the reason the drug was not put on the hospital’s formulary.

Confidential Witness No. 12

195. CW12 was an employee in support position at Portola's San Francisco headquarters from prior to the Class Period through July 2020. S/he provided support to both the Commercial Sales Division and the Medical Affairs Division.

196. CW12 stated that his/her impression of defendant Garland upon his hiring as CEO in late 2018 was that he was brought to Portola to sell the Company— it was a 'vibe' s/he and others had. While the prior CEO, William Lis, retired in 2018 (soon after the failed Bevyxxa launch), it was understood that he had been fired. CW12 said that the impression s/he and others had was that Lis did not want to sell the Company and that was why he was removed. CW12 said this was discussed with in the lunchroom as casual conversation with members of the sales team and others. According to CW12, no one trusted Garland.

197. CW12 stated that s/he was aware that the sales of Andexxa were not going well, although s/he did not have access to actual sales numbers. S/he obtained information from "lunchroom" conversation with people in the Sales Division.

198. CW12 stated that "town hall" meetings were generally held after quarterly analyst calls and announcements, and were led by Garland and others. Garland was accompanied by other members of the senior executive team, including Defendant Dier. They were held in the San Francisco headquarters with conference lines open for those calling in from other locations. CW12 stated that during "many town hall meetings," slow Andexxa sales were discussed as was the high price of the drug, which was said to be hindering sales. CW12 stated that Defendant Garland "danced around" those issues and did not address them directly. CW12 stated that when Defendant Garland spoke, many in the Sales Division just "rolled their eyes," not trusting what Defendant Garland was saying.

199. CW12 stated that in the Spring of 2019, s/he believes that sales had “come down.” CW12 recalls lunchroom conversations with sales staff, and they were asking why sales were not going well. S/he said that they seemed frustrated by the slow sales.

200. CW12 said that the Sales Division felt that they did not get enough support from the “executive team” concerning the price of Andexxa. CW12 said that sales personnel new that the price of Andexxa was affecting sales.

201. CW12 said that, at a town hall meeting held after the news of Portola’s acquisition by Alexion, Garland was asked why the Company was sold for so little. According to CW12, Garland responded that the Company hired a firm to do a valuation of the Company and they participated in the sale.

Confidential Witness No. 13

202. CW13 has been the Director of Pharmacy Services at a small, rural community hospital in the Northeast region of the United States since April 2017.

203. CW13’s hospital has had Andexxa on its formulary since October 2019 and has used it 3 times. Andexxa went through a P&T Committee review and was recommend for the formulary. According to CW13, the CEO’s approval was required because of the high cost of Andexxa. CW13 explained that it was thought that if the hospital did not include Andexxa on its formulary, it could be exposed to liability.

204. CW13 stated that the hospital limits the use of Andexxa to patients with intercranial hemorrhaging that are being treated with Xarelto or Eliquis. CW13 said that the hospital would not normally use Andexxa to treat a GI life threatening bleeding event. CW13 states that cost is the sole reason for that decision.

205. CW13 stated that his/her small, rural hospital is not equipped to treat serious life-threatening bleeding events. In those situations, patients have to be flown out. CW13 stated that although his/her hospital carries Andexxa, the nearest hospitals that would receive critical patients do not carry Andexxa and may not take patients that have already received it. S/he believes those hospitals do not carry Andexxa because of the cost.

206. CW13 stated that s/he and others at his/her hospital pressed the Portola sales representative to get the price of Andexxa lowered, and that representative said that s/he would do his/her best to get the price lowered.

207. CW13 stated that his/her hospital is trying to return expired Andexxa to Portola, but Portola has not been responding and s/he wonders if it has to do with issues with the Company's return reserves.

F. Portola's Revenue Recognition Policies and Applicable GAAP

208. As a registrant with the SEC, Portola was responsible for issuing and fairly presenting its consolidated financial statements in accordance with U.S. GAAP and SEC Rules. In this regard, SEC Regulation S-X (17 C.F.R. § 210.4-01) provides that: "Financial statements filed with the [SEC] which are not prepared in accordance with [GAAP] will be presumed to be misleading or inaccurate." 17 C.F.R. § 210.4-01(a)(1).⁴⁷

209. U.S. GAAP is the set of conventions, rules, and procedures, which constitute the professional standards of the accounting profession. During the Class Period, authoritative U.S. GAAP were promulgated by the Financial Accounting Standards Board ("FASB") and contained within the FASB's Accounting Standards Codification ("ASC"). U.S. GAAP brings

⁴⁷ Portola operates on a calendar year, starting its fiscal year on January 1 and ending it on December 31.

consistency, conformity and, over time, comparability to financial reporting. It includes not only broad guidelines of general application, but also detailed practices and procedures. Those conventions, rules, and procedures provide a standard by which to measure financial presentations.⁴⁸

210. U.S. GAAP is established in recognition of the following financial reporting objectives:⁴⁹

- a. To “provide financial information about the reporting entity that is useful to existing and potential investors, lenders, and other creditors in making decisions about providing resources to the entity” (§OB2);
- b. To provide “information about the financial position of a reporting entity, which is information about the entity’s economic resources and the claims against the reporting entity” (§OB12);
- c. To “provide information about the effects of transactions and other events that change a reporting entity’s economic resources and claims” (§OB12);
- d. To provide “information that is useful in making economic

⁴⁸ Management is responsible for preparing financial statements that conform to GAAP. See for example, professional standards adopted by the Public Company Accounting Oversight Board (“PCAOB”), PCAOB Auditing Standards (“AS”) 1001: *Responsibilities and Functions of the Independent Auditor*.

⁴⁹ See *Statement of Financial Accounting Concepts No. 8, Conceptual Framework for Financial Reporting* – Chapter 1, *The Objective of General Purpose Financial Reporting*, and Chapter 3, *Qualitative Characteristics of Useful Financial Information* (A Replacement of FASB Concepts Statements No. 1 and No. 2), Financial Accounting Standards Board (Sept. 2010), <https://www.fasb.org/resources/ccurl/515/412/Concepts%20Statement%20No%208.pdf> (“Concepts Statement No. 8”), at §§OB2, QB12, BC1.24, QC6.

decisions, ... [which] would also be helpful in assessing how management has fulfilled its stewardship responsibility”

(¶BC1.24); and

- e. To provide “relevant financial information [that] is capable of making a difference in the decisions made by users” (¶QC6).

211. The underlying conceptual framework from which U.S. GAAP is derived recognizes that financial information should faithfully represent the phenomena that it purports to represent. Faithful representation means that financial information represents the substance of an economic phenomenon rather than merely representing its legal form. Representing a legal form that differs from the economic substance of the underlying economic phenomenon cannot result in a faithful representation. To constitute a perfectly faithful representation, the representation must be complete, neutral, and free from error.

212. As set forth in FASB Concepts Statement No. 8, one of the fundamental objectives of financial reporting is to provide useful financial information to existing and potential investors, lenders, and other creditors in making decisions about providing resources to the entity, including information concerning an entity’s financial performance during the period being presented. Concepts Statement No. 8, ¶¶OB2, QC4, QC12 and QC15, state:⁵⁰

OB2. The objective of general purpose financial reporting is to provide financial information about the reporting entity that is useful to existing and potential investors, lenders, and other creditors in making decisions about providing resources to the entity. Those decisions involve buying, selling, or holding equity and debt instruments and providing or settling loans and other forms of credit.

⁵⁰ *Id.* at ¶¶OB2, QC4, QC12, QC15 (footnotes omitted).

QC4. If financial information is to be useful, it must be relevant and faithfully represent what it purports to represent. The usefulness of financial information is enhanced if it is comparable, verifiable, timely, and understandable.

QC12. ... To be useful, financial information not only must represent relevant phenomena, but it also must faithfully represent the phenomena that it purports to represent. To be a perfectly faithful representation, a depiction would have three characteristics. It would be *complete*, *neutral*, and *free from error*. Of course, perfection is seldom, if ever, achievable. The Board's objective is to maximize those qualities to the extent possible.

OC15. Faithful representation does not mean accurate in all respects. Free from error means there are no errors or omissions in the description of the phenomenon, and the process used to produce the reported information has been selected and applied with no errors in the process. In this context, free from error does not mean perfectly accurate in all respects. For example, an estimate of an unobservable price or value cannot be determined to be accurate or inaccurate. However, a representation of that estimate can be faithful if the amount is described clearly and accurately as being an estimate, the nature and limitations of the estimating process are explained, and no errors have been made in selecting and applying an appropriate process for developing the estimate.

213. Under GAAP, a misstatement or omission is material if there is “a substantial likelihood that a reasonable person would consider it important.”⁵¹ Evaluating the importance of a misstatement or omission requires that materiality be evaluated using the following two lenses: (1) is the misstatement or omission quantitatively important; and (2) is the misstatement or omission qualitatively important.⁵²

214. Quantitatively, GAAP acknowledges the practice of applying a “rule of thumb” threshold (***e.g., 5% of an item***) to provide a “preliminary” basis for evaluating materiality. ASC 250-10-S99 notes for example:⁵³

The use of a percentage as a numerical threshold, such as 5%, may provide the basis for a preliminary assumption that – without considering all relevant

⁵¹ ASC 250-10-S99-1.

⁵² ASC 250-10-S99-1.

⁵³ ASC 250-10-S99-1.

circumstances – a deviation of less than the specified percentage with respect to a particular item on the registrant’s financial statements is unlikely to be material. The staff has no objection to such a “rule of thumb” as an initial step in assessing materiality. But quantifying, in percentage terms, the magnitude of a misstatement is only the beginning of an analysis of materiality; it cannot appropriately be used as a substitute for a full analysis of all relevant considerations. ... Evaluation of materiality requires a registrant and its auditor to consider all the relevant circumstances, and the staff believes that there are numerous circumstances in which misstatements below 5% could well be material.

215. Qualitative factors are also evaluated in determining whether a misstatement is material. In this regard, **qualitative factors can render misstatements less than the quantitative 5% benchmark material.** Certain factors explicitly referenced for consideration and listed at ASC 250-10-S99 include the following relevant considerations:

- “whether the misstatement concerns a segment or other portion of the registrant’s business that has been identified as playing a significant role in the registrant’s operations and profitability”;
- “whether the misstatement hides a failure to meet analysts’ consensus expectations for the enterprise”; and
- “whether the misstatement has the effect of increasing management’s compensation –for example, by satisfying requirements for the award of bonuses or other forms of incentive compensation.”

216. The SEC established the following explicit disclosure requirements set forth in Item 303 of Regulation S-K, *Management’s Discussion and Analysis of Financial Condition and Results of Operations*:⁵⁴

- a. Describe any unusual or infrequent events or transactions or any significant economic changes that materially affected the amount of reported income from continuing operations and, in each case,

⁵⁴ 17 C.F.R. § 229.303(a)(3)(i)-(iii). *See also Commission Guidance Regarding Management’s Discussion and Analysis of Financial Condition and Results of Operations*, SEC Release No. 33-8350, 68 Fed. Reg. 75056-01 (Dec. 29, 2003).

indicate the extent to which income was so affected. In addition, describe any other significant components of revenues or expenses that, in the registrant's judgment, should be described in order to understand the registrant's results of operations.

- b. Describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.
- c. To the extent that the financial statements disclose material increases in net sales or revenues, provide a narrative discussion of the extent to which such increases are attributable to increases in prices or to increases in the volume or amount of goods or services being sold or to the introduction of new products or services.

The SEC rule states that the disclosures are “mandatory” where there is “a known trend or uncertainty that is reasonably likely to have a material effect on the registrant’s financial condition or results of operations.”⁵⁵

⁵⁵ See *Commission Statement About Management’s Discussion and Analysis of Financial Condition and Results of Operations*, SEC Release No. 33-8056, 67 Fed. Reg. 3746-02 (Jan. 25, 2002).

217. As detailed below, during the Class Period, Portola repeatedly assured investors that the Company's consolidated financial statements as filed with the SEC were fairly presented in accordance with U.S. GAAP.

218. In its FY 2018 Form 10-K, the Company set forth its revenue recognition policy ("Revenue Recognition Policy") as follows:⁵⁶

Revenue recognition

On January 1, 2018, we adopted Accounting Standards Codification ("ASC"), Topic 606 (ASC 606), *Revenue from Contracts with Customers*, using the modified retrospective method to all contracts that were not completed as of January 1, 2018. We recognized the cumulative effect of applying the new revenue standard as an adjustment to the opening balance of accumulated deficit at the beginning of 2018. The results for our reporting periods beginning on and after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period.

Pursuant to ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

Our product revenue consists of the U.S. sales of Andexxa, which we began shipping to customers in May 2018, and the U.S. sales of Bevyxxa, which we began shipping to customers in January 2018. ***Prior to January 2018 we had no***

⁵⁶ FY 2018 Form 10-K, at 60-61.

product revenues. We sell Andexxa and Bevyxxa to a limited number of specialty distributors and wholesalers in the United States (“Customers”). These Customers subsequently resell our products to hospitals, pharmacies and long-term care centers. In addition to distribution agreements with Customers, we enter into arrangements with group purchasing organizations, indirect customers and payors that provide for privately negotiated rebates, chargebacks, distribution costs and discounts with respect to the purchase of our products.

We recognize revenue on product sales when the Customer obtains control of our product, which occurs at a point in time (upon delivery). Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances. We expense incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that we would have recognized is one year or less. To date, we have not incurred any such costs.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from discounts, returns, chargebacks, rebates, copay assistance and other allowances that are offered within contracts between us and our Customers, group purchasing organizations, payors and other indirect customers relating to our product sales. These reserves as detailed below are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than a Customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted in accordance with the expected value method under ASC 606 for relevant factors. These factors include current contractual and statutory requirements, specific known market events and trends, industry data, and/or forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. ***If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.***

Trade Discounts and Allowances: We generally provide Customers with discounts which include incentive fees that are explicitly stated in our

contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we compensate our Customers and indirect customers for sales order management, data and administrative and distribution services. However, we have determined such services received to date are not distinct from our sale of products to the Customer and therefore a fair market value for these services may not be reasonably determined for accounting purposes. Therefore, these payments have been recorded as a reduction of revenue within the consolidated statement of operations for the year ended December 31, 2018.

Product Returns: We generally offer Customers a right of return based on the product's expiration date or other market-based factors for product that has been purchased from us. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We currently estimate product return liabilities using available industry data, our own sales information and our visibility into the inventory remaining in the distribution channel.

Chargebacks: Chargebacks are discounts that occur when contracted customers, which currently consist primarily of group purchasing organizations, purchase directly from our wholesalers at a discounted price. The wholesalers, in turn, charge us back the difference between the price initially paid by the wholesaler and the discounted price paid to the wholesaler by the healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and receivables. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and We generally issue credits for such amounts within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consist of (i) credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to qualified healthcare providers, and (ii) chargebacks that Customers have claimed but for which we have not yet issued a credit.

Payor Rebates: We contract with various private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of our products. We estimate these rebates and record such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

219. The FASB issued ASC 606 (*Revenue from Contracts with Customers* [Topic 606]) on May 28, 2014. ASC 606 sets forth the core principle that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the

consideration to which the entity expects to be entitled in exchange for those goods or services. ASC 606 requires every entity to evaluate every sales agreement in detail in order to recognize revenue. GAAP permits the recognition of revenue under ASC 606-10-05-4 according to the following five step process including, for purposes relevant here, Step 3 which requires a determination of the Transaction price:

- Step 1: Identify the contract(s) with a customer;
- Step 2: Identify the performance obligations in the contract;
- Step 3: Determine the transaction price;
- Step 4: Allocate the transaction price to the performance obligations in the contract; and
- Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

220. ASC 606-10-32-01 through ASC 606-10-32-14 impose additional requirements to determine the *transaction price when rights of return exist*. ASC 606-10-32-11 allowed the Company to recognize net revenues “*only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.*”

221. In assessing this revenue recognition constraint, ASC 606-10-32-12 requires the consideration of several factors which could increase the likelihood or the magnitude of a revenue reversal, including the following which are highly relevant here:

- a. The amount of consideration is highly susceptible to factors outside the entity’s influence. Th[is] ... include[s] ... a high risk of obsolescence of the promised good or service.

- b. The uncertainty about the amount of consideration is not expected to be resolved for a long period of time.
- c. The entity's experience (or other evidence) with similar types of contracts is limited, or that experience (or other evidence) has limited predictive value.
- d. The entity has a practice of either offering a broad range of price concessions or changing the payment terms and conditions of similar contracts in similar circumstances.
- e. The contract has a large number and broad range of possible consideration amounts.

G. Defendants' Representations to the Market and Market's Reaction

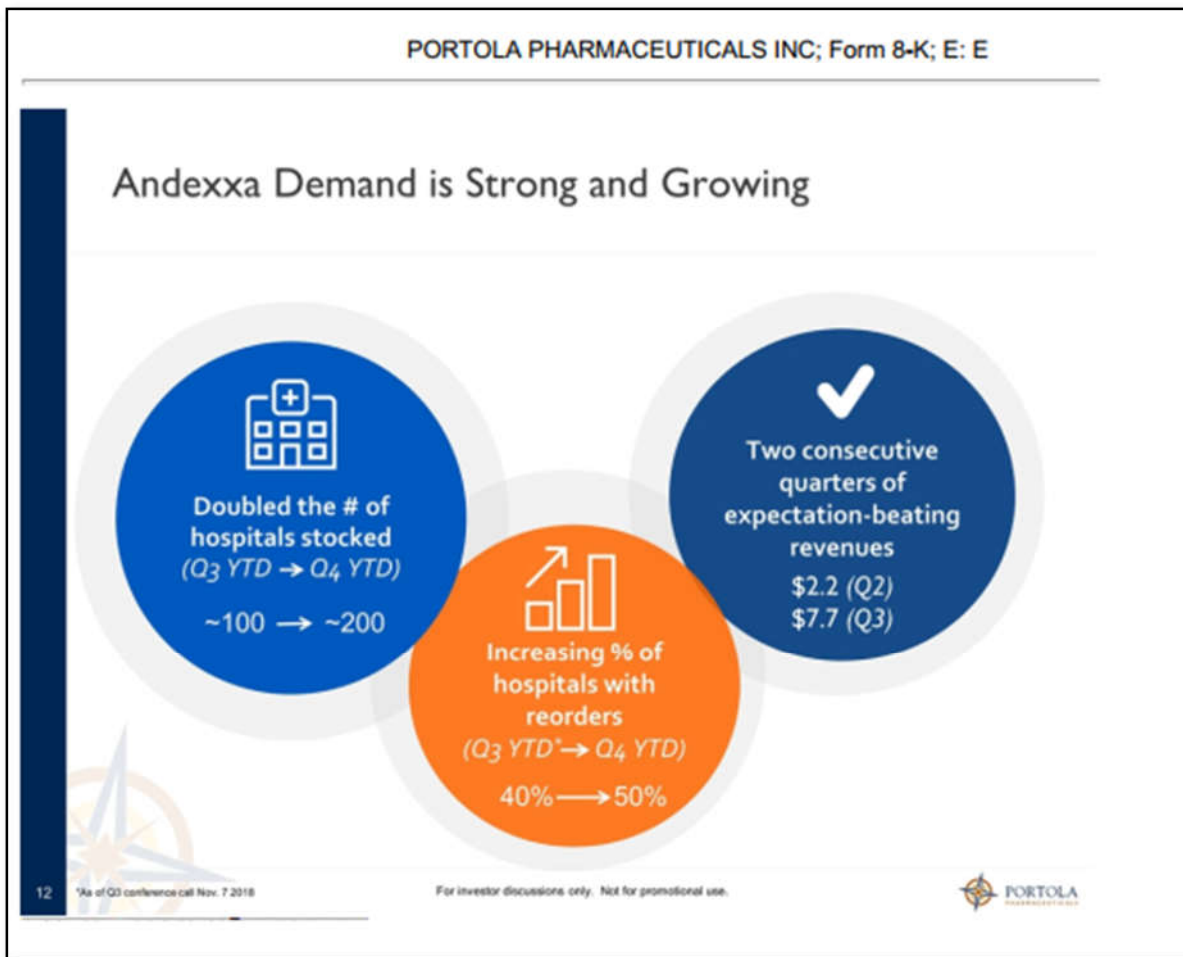
1. Portola Announces the Broad Commercial Launch of Andexxa

222. The Class Period begins on January 8, 2019, when Portola gave an investor presentation (the Jan. 8, 2019 Conference Call) announcing the broad commercial launch of Andexxa. The Company reported that following the FDA approval of the second-generation manufacturing process on December 31, 2018, the Company had officially begun shipping Andexxa to specialty distributors, which would supply hospitals in the expanded commercial launch in the United States. Garland told investors about the positive outlook of the broad commercial launch of Andexxa. Garland reported that since Andexxa first began shipping to select hospitals at the end of May 2018 through the ESP, Portola had stocked 200 hospitals, doubling the number of sites that it had begun stocking in the previous quarter. Critically, Garland also told investors that Portola had seen its reorder rate improve such that the percentage of accounts that had reordered was at 50% as of December 31, 2018: "What I can say today and what we said on our Q3 call is that we're very encouraged with the reorder rate that we're

seeing, and we believe it's truly reflective of pull-through demand. Not just stocking, but real pull-through demand."

223. In addition, Portola's Vice President of Business Development Jeet Mahal stated on the Jan. 8, 2019 Conference Call: "[I]n terms of the performance of the [ESP], . . . what we have seen and I think we're encouraged by, is what we expect, which is a time frame for these hospitals who want their stock to get activated, and that can range 3 or 4, 5, 6 months, really depends on the institution. Many of the earliest institutions were the largest academic centers, so they have a lot of processes and protocols. But once they get going, they get going on a regular basis, and that's what we're really encouraged by."

224. In the presentation materials (the "Jan. 8, 2019 Presentation"), which the Company also filed with the SEC on Form 8-K that day, Portola stated, "Andexxa Demand is Strong and Growing":



2. Fourth Quarter 2018 Financial Results

225. On March 1, 2019, the Company issued a press release (the “Mar. 1, 2019 Press Release”) announcing fourth quarter Andexxa revenues of \$14.0 million, “followed by three consecutive quarters of strong revenues and the approval of our Generation 2 manufacturing process.” Garland stated, “With the full commercial launch of Andexxa now underway in the United States, the pending approval from the European Commission anticipated in early May, and the further extension of our cash runway, we look forward to continuing our positive momentum through 2019.”

226. During a conference call on that same day (“Mar. 1, 2019 Conference Call”), Garland touted, “I’m very pleased to report Q4 2018 net revenues of \$14 million. This is our

third consecutive quarter of strong revenues for Andexxa and reflects solid demand. As mentioned during our presentation in January, approximately 200 hospitals were stocking Andexxa by the end of the fourth quarter, with a reorder rate of approximately 50%. That's double the roughly 100 hospitals that were stocking Andexxa at the end of the third quarter, with a reorder rate of approximately 40%." Dier also touted that "total revenues were \$15.3 million for the fourth quarter and \$40.1 million for the full year 2018. Total revenues for the quarter included \$1.2 million in license and collaboration revenue" and "net sales of Andexxa grew to \$14 million, a more-than-80% increase over the previous quarter and our third consecutive quarter of strong Andexxa revenues. This brings the 2018 revenues of Andexxa to \$24 million."

227. During the conference call, Garland stated when asked a direct question regarding the use of competing treatments:

[Analyst]: [W]here Andexxa is available, is it your understanding that that is clearly the first line therapy for the Xa bleeds or might there be some hospitals that while they have Andexxa available, are still using some of the older methods like fresh frozen plasma or four-factor PCCs even though that Andexxa is available?

[Garland]: Certainly, we know hospitals are using PCCs and we expect they probably will continue to use PCCs although we believe that's inappropriate given the fact that we're the only approved agent. But in many ways you call it, it really does vary by hospital. *It's kind of hard to speak about it generally because each hospital is somewhat unique.*"

228. Also, that same day, an analyst from Cowen noted in a report that Portola's \$14 million Andexxa sales beat his estimate of \$10.1 million and the consensus of \$9.4 million.

229. On March 1, 2019, the Company filed its FY 2018 Form 10-K reporting its detailed its distribution practices for the Andexxa broad commercial launch and its method for recognizing revenue:

We sell Andexxa and Bevyxxa to a limited number of specialty distributors and wholesalers in the United States (“Customers”). These Customers subsequently resell our products to hospitals, pharmacies and long-term care centers. In addition to distribution agreements with Customers, we enter into arrangements with group purchasing organizations, indirect customers and payors that provide for privately negotiated rebates, chargebacks, distribution costs and discounts with respect to the purchase of our products. We recognize revenue on product sales when the Customer obtains control of our product, which occurs at a point in time (upon delivery). Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

230. In describing how Portola determines net product revenue, the FY 2018 Form 10-K stated:

Our product revenue consists of the U.S. sales of Andexxa, which we began shipping to customers in May 2018, and the U.S. sales of Bevyxxa, which we began shipping to customers in January 2018 ... In addition to distribution agreements with Customers, we enter into arrangements with group purchasing organizations, indirect customers and payors that provide for privately negotiated rebates, chargebacks, distribution costs and discounts with respect to the purchase of our products.

We recognize revenue on product sales when the Customer obtains control of our product, which occurs at a point in time (upon delivery). Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

231. In the FY 2018 Form 10-K, Portola described its process for establishing “Reserves for Variable Consideration,” which included “discounts, returns, chargebacks, rebates, copay assistance and other allowances” that are to be factored into the Company’s reported revenues. Specifically, the FY 2018 Form 10-K stated:

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from discounts, returns, chargebacks, rebates, copay assistance and other allowances ... Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted in accordance with the expected value method under ASC 606 for relevant factors. These factors include current contractual and statutory requirements, specific known market events and trends, industry data, and/or forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

232. The FY 2018 Form 10-K described the variable considerations that were purportedly factored into the Company's revenues, stating:

Product Returns: We generally offer Customers a right of return based on the product's expiration date or other market-based factors for product that has been purchased from us. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We currently estimate product return liabilities using available industry data, our own sales information and our visibility into the inventory remaining in the distribution channel.

233. The FY 2018 Form 10-K, which characterized as merely "[r]isks related to commercial and marketing operations" that Portola's "[f]ailure to attain market acceptance among the medical community and third-party payors *may* have an adverse impact on our operations and profitability," and "*if* we are not successful in commercializing Andexxa, our future product revenue will suffer, we *may* incur significant additional losses and our business will be materially harmed."

234. The FY 2018 Form 10-K furthers stated that "Andexxa *may compete* with the off-label use of other treatments designed to enhance coagulation, such as FFP, PCCs, rFVIIa or whole blood. Although there is no approved indication for these products in patients taking Factor Xa inhibitors, physicians may choose to use them because of familiarity, cost or other reasons."

235. The FY 2018 Form 10-K further stated that "[t]he accompanying financial statements have been prepared in accordance with accounting principles generally accepted in

the United States ('U.S. GAAP')." The Company reported product revenues of \$24.1 million and a loss of \$350.2 million for FY 2018.

236. The FY 2018 Form 10-K was signed by Garland and Dier and contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX" or "SOX Certification") by Garland and Dier attesting to the purported accuracy and completeness of the Company's financial and operational reports as well as statements concerning Portola's internal controls and procedures, as follows:

1. I have reviewed this annual report on Form 10-K of Portola Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting

and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

- (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

237. In yet a further certification appearing as Exhibit 32.1 to the FY 2018 Form 10-K, Garland and Dier both certified that “[t]he information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.”

3. First Quarter 2019 Financial Results

238. On May 8, 2019, the Company issued a press release announcing its financial results for the first quarter ended March 31, 2019 (“May 8, 2019 Press Release”). The Company reported total revenues of \$22.2 million for the first quarter of 2019, compared to \$6.6 million for the first quarter of 2018. Total first quarter revenues included \$20.3 million in net product revenues from Andexxa sales, or 45% more than the previous quarter. In the Company’s earnings release, Garland represented that “our first quarter results continue to reflect strong demand for Andexxa, as well as focused execution on our commercial launch.”

239. Later that day, the Company conducted an earnings call, the May 8, 2019 Conference Call where Garland, Dier, and Koenig reported Q1 2019 Andexxa net revenue of \$20.3 million; Garland reported total net revenue of \$22.2 million; and Dier touted the Company “had a strong first quarter with Andexxa revenues growing 45% of its fourth quarter and expenses in line with our guidance for the full year.” Despite previous and ongoing discussions about the strength of demand and its linear growth, when asked to “break out the revenue ... recognized by initial orders versus reorders in the quarter” Koenig deflected, stating, “We haven’t done that [sic] we won’t be doing that on this call.”

240. Koenig also represented that the “daily demand [for Andexxa] continue[s] to grow” as “hospitals will continue to come online at a rate that is approximately consistent with what we have seen in the last few quarters.” Garland added that the Company was “very happy with what we’ve been seeing so far with the reorder rate” from hospitals, as those “reorder rates are really reflecting ... pull through and underlying demand.” Furthermore, Garland represented that there was “enthusiasm and the desire from what we might call a nontarget hospital to stock this drug,” which therefore “speaks both to the significant value of the drug as well as the desire

to use the product as quickly as possible.” Accordingly, Garland underscored that he was “actually very, very pleased with the uptake of Andexxa so far” and “expected that the current trajectory should continue at a linear rate” with respect to revenues, as the “utilization on a per hospital level ... deepen[s] both as physicians get used to the product and as hospitals continue to go through their protocol development[.]”

241. Koenig also stated on the May 8, 2019 Conference Call that “the amount of inventory with our distributors remain relatively constant throughout the quarter and is in line with industry norms.” Koenig also noted that the Company is “seeing that the utilization of Andexxa is both in ICH bleeds and also in other bleeds outside of ICH. So we’re seeing a mix of all types of bleeds that are currently being treated.” Similarly, Garland represented that he was “pleasantly surprised by the fact that [the] drug is being used broadly.”

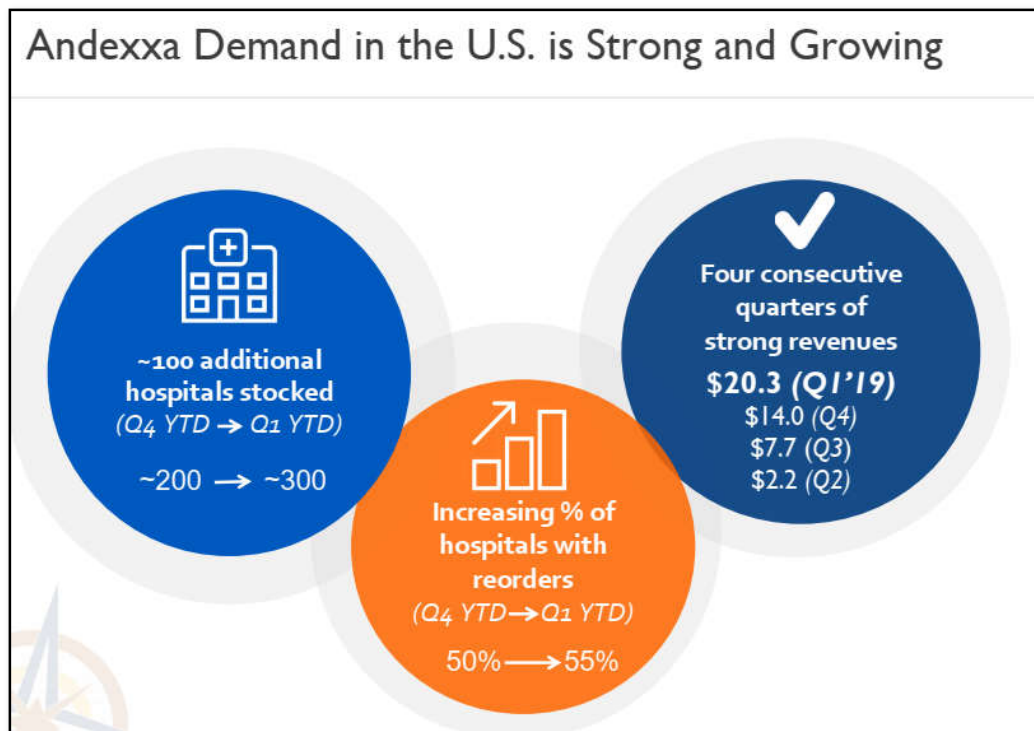
242. When asked by an analyst to comment on timelines to go through “the hospital protocol review for Gen 2 relative to Gen 1,” Koenig stated, “So the review as it relates to [P&T] committees booking at the product regardless of that whether it’s Gen 1 or Gen 2 is technically a six to nine month process And this is certain industry norms. And ... one of the things we’ve said all along is that we expect that rate to continue at a pretty linear rates to exactly what we’re saying *and totally in line with our expectations.*”

243. Koenig soon after represented that the majority of the Company’s 300 hospital customers *had conducted those hospital protocol reviews and made their P&T determinations*—a shorthand reference to hospitals’ policies regarding the utilization of drugs, therapies, and drug-related products and identifying those that are most cost-effective and medically appropriate for the hospital’s patient population (also known as a “formulary system”). *Specifically, Koenig told investors that “[t]he majority of hospitals have made P&T decisions.*

So the majority of them have the product on the protocol and are using the product. As we mentioned earlier, happy with the rate of reorder rates that we are currently seeing.”

244. Further pressed by an analyst’s question about how many of those “300 start hospitals have the protocols in place today versus which ones ... still need to evolve them over time,” Garland made clear that the majority had them firmly in place: *“The majority of hospitals have made P&T decisions. And so the majority of them have the product on the protocol and are using the product....”*

245. In the presentation materials used on the May 8, 2019 Conference Call (the “May 8, 2019 Presentation”), Portola stated, “Andexxa Demand in the U.S. is Strong and Growing”:



246. On that same day, an analyst from Cowen noted that Andexxa’s \$20.3 million of sales were in-line with his estimates and consensus estimates of \$20 million. The Cowen analyst noted, “Management declined to quantify the revenue contribution from hospital

stocking versus end-user demand, but indicated that in January specialty distributors purchased ~\$2MM in initial inventory and that inventory remained relatively constant throughout the quarter, in-line with industry norms.” The Cowen analyst also recounted that “Portola has been adding ~100 hospitals per quarter and suggested on the call this morning that the pace of hospital addition is expected to continue at a linear rate. Andexxa continues to undergo P&T reviews at institutions, a process which Portola estimates typically takes 6-9 months.”

247. On May 8, 2019, the Company also filed with the SEC a quarterly report on Form 10-Q for the first quarter of 2019, which covered the first three months of 2019 ending on March 31, 2019, reporting Q1 2019 product revenues of \$20.3 million for Andexxa sales (“Q1 2019 Form 10-Q”). In its Q1 2019 Form 10-Q, the Company reported revenues of \$22.2 million.

248. The Q1 2019 Form 10-Q stated that “[t]he unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (‘U.S. GAAP’), and follow the requirements of the Securities and Exchange Commission (‘SEC’) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP has been condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as our annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of our financial information. The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for

the year ended December 31, 2018 included in our Annual Report on Form 10-K filed on March 1, 2019 with the SEC.”

249. The Q1 2019 Form 10-Q was signed by Garland and Dier and contained signed SOX Certifications by Garland and Dier attesting to the purported accuracy and completeness of the Company’s financial and operational reports as well as statements concerning Portola’s internal controls and procedures, as follows:

1. I have reviewed this quarterly report on Form 10-Q of Portola Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external

purposes in accordance with generally accepted accounting principles;

- (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

250. In the Q1 2019 Form 10-Q, the Company represented that Portola's operations "may be affected by a variety of factors, including: the level of demand and market acceptance," and that the Company's success depended on the "degree of market acceptance," "the willingness of physicians and healthcare organizations to change their current treatment practices," and "the willingness of hospitals and hospital systems to include our products as treatment options."

251. On July 8, 2019, Portola issued the July 8, 2019 Press Release announcing new in vitro data establishing the relationship between concentrations of the direct oral anticoagulants apixaban and rivaroxaban and the ability of 4F-PCC to correct inhibition of thrombin generation, compared with warfarin anticoagulation reversal by 4F-PCCs, such as Kcentra.⁵⁷ This was the first press release issued by Portola attacking 4F-PCCs during Andexxa's commercial launch.

4. Goldman Sachs Global Healthcare Conference

252. On June 11, 2019, Garland participated in the Goldman Sachs Global Healthcare Conference ("June 11, 2019 Goldman Sachs Global Healthcare Conference Call"). Garland represented that the Company "track[s] the number of accounts that have ordered at least once," stressed that on a quarter-on-quarter basis, Portola had "about 100 new hospitals ordering each quarter," and touted that there was "enough data to feel very confident in both the short- and the long-term trajectory of Andexxa," and "[w]e've now had 4 quarters of very solid revenue, the most recent of which was \$20.3 million net."

253. At the conference, Garland made clear that the Company's singular focus was Andexxa in response to an analyst's question:

[Analyst]: So for investors who are maybe new to the story, it *seems it's Andexxa, Andexxa, Andexxa*. But I'm sure as a company, there might be strategic vision over the next several years, let's just call it 5 years, where does Portola want to be?

[Garland]: ... *Right now, as you just said, we're focused on Andexxa. And I think it's important we stay focused on Andexxa* because we've got to get people confident we can execute and confident that we've got an asset that is going to be of great value.

⁵⁷ Press Release, Portola, *Portola Pharmaceuticals Presents New In Vitro Data Demonstrating that Four-Factor Prothrombin Complex Concentrates (4F-PCCs) Had No Direct Effect on Inhibition of Thrombin Generation by Factor Xa Inhibitors* (July 8, 2019).

5. Second Quarter Financial Results

254. On August 7, 2019, Portola issued a press release announcing its financial results for the second quarter ended June 30, 2019 (“Aug. 7, 2019 Press Release”). The Company reported that Andexxa net product revenues grew to \$27.1 million of the Company’s total revenue in the quarter of \$28.4 million, compared to only \$4 million during the same period for the prior year. In the Company’s earnings release, Garland touted “this is our fifth consecutive quarter of strong revenue growth reflecting our exceptional launch execution and continued demand for Andexxa.” On this news, shares of Portola traded up \$3.22 or 11.9% to closed at \$30.36 per share on August 8, 2019, on heavy volume.

255. During the earnings call later in the day, the Aug. 7, 2019 Conference Call, Dier represented that “[t]otal revenues were \$28.4 million for the second quarter driven by \$27.1 million in net revenues of Andexxa.” In addition, Koenig represented that to continue to optimize its targeting efforts, the Company was “deepening utilization within existing accounts” and that it was “seeing encouraging trends.” Koenig further represented that there was “continued strength and demand for Andexxa” as “74% of our sales in the quarter came from reorders, reflecting real pull-through and increasing use in patients.”

256. Also, on the earnings call, Garland touted: “[O]ur team’s exceptional execution on the launch of Andexxa is driving continued revenue growth. For the second quarter, net product revenues for Andexxa were \$27.1 million, marking our fifth consecutive quarter of strong revenue.” He further represented that Andexxa was “one of the top five hospital drug launches over the last 30 years.” Garland said that Portola tracked the type of usage of Andexxa by hospitals as a metric of deepening utilization, saying, “We do track that. We do track it with a chart [or poll]. What we have said in the past and what’s very encouraging is

that we are definitely seeing usage in patients outside of the intracranial hemorrhage space.”

Garland also reaffirmed, “There’s deepening of usage in existing accounts.”

257. Later, on the Aug. 7, 2019 Conference Call, Garland responded to a question by an analyst concerning utilization as follows:

[Analyst]: Does it concern among investors that over time as you get later doctors to stock a drug, their utilization is going to be less than the people who have stocked already. So the revenue curve is going to—going to begin to plateau or decelerate. What are your—what are your thoughts on that concern that’s in the market.

[Garland]: ... What we are seeing, as we’ve looked at a cohort of our institutions, large important institutions that came on earlier at [ESP] *and actually what we’re seeing is increased usage over time or deepening usage over time. There’s nothing that we’re seeing today that makes us concerned about a lack of pull-through or a plateauing of our utilization.*

258. Garland also proclaimed, “Also last week, the Joint Commission known as JCAHO, the oldest and largest accrediting body for hospitals and med care [ph] issued a new report on DOACs. The report directs accredited hospitals and critical care centers to stock anecdotes appropriate for the use with each type of anticoagulant. *Reports like these are making it clear that Andexxa is becoming the standard of care for patients on apixaban or rivaroxaban.*”⁵⁸

259. In the presentation materials used on the Aug. 7, 2019 Conference Call (“Aug. 7, 2019 Presentation”), Portola stated, “Andexxa Demand in the U.S. is Strong and Growing”:

⁵⁸ A review of The Joint Commission *Sentinel Event Alert* on July 30, 2019, reveals that Andexxa was not specifically mentioned in this article. See <https://www.jointcommission.org/resources/patient-safety-topics/sentinel-event/sentinel-event-alert-newsletters/sentinel-event-alert-61-managing-the-risks-of-direct-oral-anticoagulants/>.



260. In a report issued that same day, an analyst at Cowen noted that Andexxa sales of \$27.1 million were above the consensus of \$24.0 million and his estimate of \$25 million. Similarly, a Credit Suisse analyst commented, “While reorder rates have remained stable at 55%, the above-expectations hospital adds and a concentration towards the end of the quarter impacted the metric and the company indicated that earlier adopting hospitals have a higher reorder rate and deepening usage. Management highlighted that 74% of revenues this quarter were from reorders, potentially reflecting real underlying demand and hospital utilization of Andexxa.”

261. On August 7, 2019, the Company also filed a quarterly report on Form 10-Q with the SEC for the second quarter of 2019, which covered the three months of 2019 commencing on April 1, 2019 and ending on June 30, 2019, reporting Q2 2019 product revenues of \$27.1 million (“Q2 2019 Form 10-Q”).

262. The Q2 2019 Form 10-Q stated that “The unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting

principles ('U.S. GAAP'), and follow the requirements of the Securities and Exchange Commission ('SEC') for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP has been condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as our annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of our financial information. The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2018 included in our Annual Report on Form 10-K filed on March 1, 2019 with the SEC."

263. The Q2 2019 Form 10-Q represented that Portola's operations "may be affected by a variety of factors, including: the level of demand and market acceptance," and that the Company's success depended on the "degree of market acceptance" and "the willingness of physicians and healthcare organizations to change their current treatment practices" and "the willingness of hospitals and hospital systems to include our products as treatment options."

264. The Q2 2019 Form 10-Q was signed by Garland and Dier and contained signed SOX Certifications by Garland and Dier that are identical to the ones signed in Q1 2019.

6. August 2019 Public Offering

265. On August 7, 2019, the Company filed a Registration Statement on Form S-3 which included a base prospectus ("Registration Statement" or "August 7, 2019 Base Prospectus") with the SEC. The Registration Statement became effective on August 7, 2019. On August 12, 2019, Portola filed a Preliminary Prospectus Supplement on Form 424(b)(5)

with the SEC (“August 12, 2019 Preliminary Prospectus”), which preliminarily announced a public offering. On August 14, 2019, the Company filed a Prospectus Supplement on Form 424(b)(5) with the SEC (collectively with the August 7, 2019 Base Prospectus, August 12, 2019 Preliminary Prospectus Supplement, the “Prospectus”). In the Registration Statement and Prospectus, Portola incorporated by reference the following Company documents: (a) the FY 2018 Form 10-K; (b) Q1 2019 Form 10-Q; and (c) Q2 2019 Form 10-Q. These materials, along with the Registration Statement and Prospectus, are collectively referred to herein as the “Offering Materials.” As the Offering Materials stated, the “information incorporated by reference is considered to be part of” the Registration Statement and Prospectus.

266. Portola sold 9,241,072 shares of common stock in the Offering, which included 1,205,357 shares of common stock issued pursuant to the over-allotment option granted to the underwriters, at a public offering price of \$28 per share. The total proceeds from the Offering and over-allotment, net of underwriting discounts and commissions of approximately \$14.2 million, were approximately \$244.5 million.⁵⁹

267. In the Offering Materials, the Company specifically touted the success of the Andexxa commercial launch along other metrics such as “reorder rate”: “Andexxa is tracking with the most successful among 45 other acute care hospital drugs launched in the past 30 years based on average quarterly sales for the first four full quarters of launch. In addition, in the second quarter of 2019, Andexxa had a reorder rate of 54% with 74% of Andexxa revenues from reorders for the quarter. In the same period we added 125 additional hospitals for a total of over 400 hospitals that have ordered Andexxa since launch.”

⁵⁹ FY 2019 Form 10-K, at F-9.

7. Morgan Stanley Global Healthcare Conference

268. On September 10, 2019, during the Morgan Stanley Global Healthcare Conference Call (“Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call”), Garland announced “\$27.1 million in net revenues for Andexxa” and assured investors of Andexxa’s “broad utilization” and emphasized that Portola was hearing “from our physicians ... a lot of enthusiasm for the drug, high unmet medical need, very limited treatment options and a very large and growing problem that is urgent and life-threatening.” To bolster his assertion of Andexxa’s “broad utilization,” Garland cited internal metrics on the increasing number of hospitals making their first, second, and third purchases of Andexxa; a “regular chart audit” of hospital records for patients who have been given Andexxa; and an internal benchmark analysis purportedly ranking Andexxa “in the top 5” of 45 comparable drug launches in the past 30 years. Garland further assured investors that his focus was “first and foremost” on Andexxa, which was Portola’s “first, second, third priority.” Garland said that all of this “gives a really positive picture about the future projections of this drug, both in short and long term.” Garland specifically stated:

The reorder rate, we’ve talked about before, it was 55%, which was stable quarter-on-quarter, is heavily influenced by when a hospital comes online. And remember, we added 125 hospitals in the second quarter. Many of those were later in the quarter. And as a result, they are in the denominator, but they haven’t been around long enough to contribute to the numerator. ***So that had an impact on the reorder rate, which is why we gave it a new metric, which was that roughly 3/4 of our business, or 74% of our business, came from reorders.*** So what we’re seeing consistently is that the drug is getting utilized.

8. Third Quarter Financial Results

269. On November 5, 2019, the Company issued a press release announcing its financial results for the third quarter ended September 30, 2019 where it reported total global revenues of \$36.8 million, compared to \$14.2 million for the third quarter of 2018 (“Nov 5,

2019 Press Release”). Total global revenues included \$35.7 million in net product revenues from sales of Andexxa/Ondexxa. In the release, Garland represented that the Company had “delivered another quarter of strong Andexxa revenue in the U.S.” and “will continue to focus on exceptional launch execution, leveraging external support from health authorities and favorable society guidelines, and building the clinical evidence and awareness of Andexxa” as the “use of Factor Xa inhibitors in both markets continues to grow, driving the underlying market opportunity for Andexxa/Ondexxa and long-term value of Portola.”

270. Later that day, the Company conducted an earnings call (“Nov. 5, 2019 Conference Call”). In the presentation materials used during the call (“Nov. 5, 2019 Presentation”), Portola stated, “Andexxa Demand is Strong and Growing”:



271. Garland represented during the Nov. 5, 2019 Conference Call that Portola “remain[s] confident in our ability to build long-term growth and value” and that “the demand for Andexxa was strong” because of continued execution on Andexxa’s launch, the rapid growth of the Factor Xa inhibitor market, and Portola’s success in establishing Andexxa as “the standard of care.” Garland further represented, “Our revenue is being driven by new customer additions

and positive utilization trends,” that “[i]n the third quarter, net product revenue for Andexxa were \$35.7 million. This includes \$33 million in net product sales for Andexxa in the United States and \$2.7 million in net product sales of Ondexxya in our wave 1 countries in Europe,” and that “[w]e also hit an exciting revenue milestone in the third quarter surpassing \$100 million in cumulative net sales since our launch in May of 2018.”

272. Dier represented at the Nov. 5, 2019 Conference Call that, “Total revenues were \$36.8 million for the third quarter driven by \$35.7 million in global net revenues of Andexxa.” Koenig touted “These initial revenues of \$2.7 million reflect demand since the majority of sales to date are direct to hospitals, unlike the U.S., where we distribute via wholesalers. All of this underscores the unmet need and demand in Europe for Andexxa.” He further represented that “[e]xisting accounts continued to show strong pull-through, with 76% of sales in the quarter coming from utilization or reorders compared to 74% in the previous quarter” and “[t]his is an important metric because it reflects demand and significant pull-through in the hospitals where Andexxa is being used to treat patients.” He further stated, “Inventory in the channel remained steady at approximately two weeks of demand” and described the U.S. market as “very data-rich” for use in tracking orders. Further when asked by an analyst whether Portola was “still conducting [a] quarterly chart review and if [the Company] could comment on what sort of bleeds you’re seeing Andexxa is used for in the U.S. and how that may be evolving over time,” Koenig responded, “So we do still continue our chart review on a quarterly basis. And similar to what we’ve reported in our previous quarters, Andexxa is being used in all ranges of bleeds.”

273. During the Nov. 5, 2019 Conference Call, Garland responded to specific analyst concerns regarding utilization during the year as follows:

[Analyst]: And then now with a year of experience on the U.S. market, I’m just wondering if you could start to give us some kind of comparison or, if it’s high

level, even about the current utilization at some of those hospitals that have been online for at least a year, maybe even over a year, versus maybe some that have come online in the past six months....

[Garland]: [N]ow that we've got a couple of years under—or a year under our belt how does the utilization look[?] We aren't giving any detailed information around utilization per hospital per month. *What we have seen is that, that utilization per hospital per month stays—has been staying consistent in 2019.*"

[Analyst]: [O]n the 76% of sales, revenue driven by reorders, can you just comment on where you see that number trending? And it seems like it's leveling off a bit. Is that how – what you expect at this point in the launch?

[Garland]: [W]e haven't and won't be providing any sort of forward-looking guidance on the reorder rate. It obviously went up quarter-over-quarter. I do expect, though, that, that number is not going to be 100%.

274. Despite the unwavering optimism expressed by Garland and Koenig about new hospital adds driving revenue and linear growth, among other things, Garland punted on whether the Company was in a position to offer guidance for 2020:

[Analyst]: So at this point in the launch for Andexxa, do you think you have enough confidence in the predictability of sales that you'd be providing revenue guidance for 2020?

[Garland]: We're still evaluating that. Obviously we now have a year underneath us.

An analyst report issued by Cowen that same day stated that "Andexxa/Ondexxya sales of \$35.7MM (+32% Q/Q), above consensus of \$33.6MME and our \$32.0MME... 76% of Q3 U.S. sales were from re-orders reflecting genuine pull-through of the product. On the call tonight, Portola indicated that the proportion of hospitals reordering

275. per quarter (56% by the end of Q3:19) is subject to variability due to the timing, mix, and order of hospital additions during the quarter, and this figure will no longer be provided in the future."

276. On November 5, 2019, the Company also filed a quarterly report on Form 10 Q with the SEC for the third quarter of 2019, which covered the three months of 2019 commencing on July 1, 2019 and ending on September 30, 2019 (“Q3 2019 Form 10-Q”), affirming the previously reported financial results including \$32.95 million for Andexxa net product revenues for the third quarter. The Q3 2019 Form 10 Q reported that for the nine-months ending September 30, 2019, Andexxa had \$80.3 million in net product revenues.

277. The Q3 2019 Form 10-Q stated that “[t]he unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (‘U.S. GAAP’), and follow the requirements of the Securities and Exchange Commission (‘SEC’) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP has been condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as our annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of our financial information. The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2018 included in our Annual Report on Form 10-K filed on March 1, 2019 with the SEC.”

278. In the Q3 2019 Form 10-Q, the Company represented that Portola’s operations “may be affected by a variety of factors, including: the level of demand and market acceptance,” and that the Company’s success depended on the “degree of market acceptance” and “the willingness of physicians and healthcare organizations to change their current

treatment practices” and “the willingness of hospitals and hospital systems to include our products as treatment options.”

279. The Q3 2019 Form 10-Q was signed by Garland and Dier and contained signed SOX Certifications by Garland and Dier that are identical to the ones signed in Q1 2019.

280. On November 6, 2019, Oppenheimer issued a research report stating “Andexxa 3Q revenues of ~\$36M exceeded our estimate and consensus estimate, both at ~\$33M, by adding 125 new US hospitals for a total of 550 now stocking Andexxa.” Further, “[m]anagement indicates US inventory levels were essentially constant during the quarter with no incremental stocking....” The report also noted that “[t]he 56% reorder rate in 3Q increased slightly from 2Q and is potentially misleading based on a large number of hospitals added toward the end of 3Q.” However, “[m]anagement describes reorders as a % of total revenues as a more meaningful metric compared to the reorder rate. In 3Q, 76% of revenues were from reorders, up slightly from the 74% in 2Q.”

281. On November 15, 2019, Portola issued a press release announcing that the Annals of Emergency Medicine, the journal of the American College of Emergency Physicians (“ACEP”), published a multidisciplinary anticoagulant reversal and replacement guidance statement. In the guidance statement, ACEP highlighted Andexxa as a first-in-line, FDA-approved reversal agent for patients treated with apixaban or rivaroxaban, “as compared to 4F-PCC [e.g., Kcentra], which are highlighted as a second-in-line option for Factor Xa reversal and recommended for use only if Andexxa is not available.”⁶⁰

⁶⁰ Press Release, Portola, *Andexxa Highlighted as a First-Line Factor Xa Reversal Option by the American College of Emergency Physicians* (Nov. 15, 2019).

H. The Truth Starts to be Revealed

1. Portola Admits that Andexxa Demand is Flat, Utilization is Decreasing and the Company Under-Reserved for Product Returns and Sold Excessive Product to Its Specialty Distributors

282. After market close on January 9, 2020, Portola issued a press release (“Jan. 9, 2020 Press Release”) stating that total net U.S. Andexxa revenues were projected to be \$24 million for the fourth quarter of 2019, down from \$33 million the prior quarter, a decline of 27%, and that global net revenues were projected to be \$28 million for the quarter, which was 32% lower than the consensus estimate of \$41 million. The press release stated that fourth quarter Andexxa net sales in the U.S. were impacted primarily by two factors: (i) a “\$5 million gross to net adjustment due to a return reserve for short-dated product”; and (ii) “[f]lat quarter over quarter demand due to a decrease in utilization, primarily in tier 1 accounts.” Portola further stated that it “believes that in certain of these accounts, hospital pharmacies curtailed use of Andexxa following drug utilization reviews in an effort to manage pharmacy budgets.”

283. During a conference call at 5:00 p.m. ET on January 9, 2020 (“Jan. 9, 2020 Conference Call”), one analyst asked, “On the gross-to-net, you mentioned \$5 million in this quarter due to returns. What had been your typical gross-to-net been in prior quarters? Dier responded that “[w]e haven’t given our gross-to-net estimate publicly, but the \$5 million does represent short-dated product return reserve adjustment for this quarter. So obviously, that had an impact on the gross to net, but that represents a little bit of a catch-up and a little bit about what we project going forward for the short-dated product.”

284. Dier further explained that “[w]e do think this onetime adjustment takes in effect a little bit of what came back *during the year* and what may come back going forward with some short-dated products still outstanding. *But going forward, our reserves will be calculated into our gross to net on a more normalized basis.* And like I said, we’re already

starting to shift the long-dated 36-month product. We started that in November. So we feel good about this one adjustment.”

285. When asked by an analyst in the same conference call whether the “\$5 million reserve is for product that is short-dated, but has not yet been returned,” Dier responded that the reserve addresses “both” “what’s been returned, *it’s a little bit of catch-up for the year*, and then you need to make an estimate of what you think may be returned based on what you’ve seen so far. *That’s just accounting for return reserves....* So we come up with a calculation. We feel good about the \$5 million, taking the \$5 million now. *And then moving forward, we’ll have our classic return reserve adjustment as part of our gross-to-net calculations....* I’ll just reiterate again, the longer-dated product has already stated selling as of November, and that’s 36 months.”

286. On this issue, Koenig further noted, “On the short-dated product, it was ... *between 6 and 12 months*. And the reason why the decision was made to go out with that dating was to get the medicine to patients as quickly as possible.” Garland added, “And Jay, I should emphasize that the dating of 6 to 12 months is when it got to the distributor. *What the actual dating was when it was shipped to the end customer, we don’t have that visibility, but that’s essentially what it was when we shipped to our distributors.*”

287. On this news, the Company’s share price plummeted by \$9.98, or approximately 40%, to close at \$14.76 per share on January 10, 2020 on unusually heavy trading volume. Meanwhile, the Nasdaq Composite Index and the Nasdaq Biotech Index decreased 0.4% and 0.3% respectively, on January 10, 2020.

288. This news was a major resetting of expectations with regard to Andexxa. Following this news, analysts (including Oppenheimer, Cowen, Credit Suisse, and Morgan

Stanley) downgraded their ratings and/or lowered their price targets for Portola stock in response to the announcement of flat demand due to a decline in utilization and preliminary results that were significantly below consensus estimates.

289. For example, in its January 9, 2020 report, Cowen noted, “***Q4 sales were hurt by lower utilization*** at early-adopting Tier 1 hospitals. Management notes many held drug utilization reviews and these resulted in the requirement for a physician or pharmacy consult prior to use of Andexxa. Though management does not think the reviews produced specific restrictions on which patients can get Andexxa, ***the revenue numbers clearly suggest that the consults are resulting in fewer patients getting the antidote.... We are concerned by this decrease in utilization.*** Though management outlined a number of measures it will take to deepen utilization during 2020, we suspect that these will take time to have an impact. Moreover, as the reviews were undertaken by early-adopters, other hospitals could be expected to perform them over time. ***This implies Andexxa will ramp more slowly than we had projected.*** We are cutting our estimates for 2020-22.”

290. On January 10, 2020, Credit Suisse lowered its target price for Portola stock from \$35 per share to \$18 per share, also raising concerns of a “high burn rate (2020 consensus OpEx of ~\$340m vs \$464m cash balance).” Credit Suisse noted, “Portola reported Q4’19 revenue of ~\$28m, which came in substantially below FactSet consensus of ~\$41m, and was 22% lower than Q3 2019 revenue of ~\$36m.” Credit Suisse also stated, “PTLA sees the health economic data as a key component to support/incentivize use of Andexxa, since no such data is available currently.”

291. Further, Oppenheimer issued a January 10, 2020 report on Portola stating it was “[m]oving to the [s]idelines on Andexxa [h]eadwinds” because the utilization reviews “signal hospital interest in Andexxa likely crossed a critical threshold.”

292. In a January 10, 2020 report titled: “Disappointing Andexxa Prerelease Resets Valuation as Concerns on Utilization Trends Grow,” William Blair stated, “The decreased utilization at tier-1 accounts is the most worrisome update, which management believes is due to hospital pharmacies curtailing the use of Andexxa following drug utilization reviews and determining the impact on pharmacy budgets. Management continues to highlight that physician demand remains strong; however, the decline in utilization raises serious concerns regarding the growth trajectory of Andexxa, particularly in the near term.”

293. Portola’s stock price continued to fall on the next trading day to close down 6.2% at \$13.84 on January 13, 2020 on heavy trading. Meanwhile, the Nasdaq Composite Index increased 1.0% and the Nasdaq Biotech Index fell 1.2% on January 13, 2020.

294. On January 14, 2020, Garland participated in a conference call (the “Jan. 14, 2020 Corporate Update Call”) where he revealed that, in addition to the two factors disclosed in the Company’s fourth quarter 2019 earnings release, Andexxa’s net *revenues were also impacted by “lower distributor purchases to manage inventory” in order “to keep their inventory levels at a constant level in the fourth quarter.”* In doing so, Portola essentially admitted that its distributors were so overstocked with Andexxa product that they had stopped ordering new inventory or reduced their orders. Garland also stated that a typical utilization review occurs “every 6 to 12 months.”

295. During this January 14, 2020 presentation, Portola further disclosed that Andexxa's net revenues were also impacted by "***lower distributor purchases to manage inventory***" in order "to keep their inventory levels at a constant level in the fourth quarter."

296. During this call, Portola used the same form of investor presentation used during the Class Period but removed the slide from the Company's three prior earnings presentations that "Andexxa Demand is Strong and Growing." The presentation materials used on the call also detailed three factors that had primarily impacted fourth quarter sales:

Andexxa Q4 Results and Business Trends in 2019			
	4Q19	FY 2019	80% of revenue from reorders in Q4, up from 78% in the third quarter
Andexxa Revenue (M)	\$28	\$111	Fourth quarter sales were impacted primarily by: <ul style="list-style-type: none"> \$5 million gross to net adjustment due to return reserve for short-dated product Flat Q/Q demand due to a decrease in utilization, primarily in Tier 1 accounts Lower distributor purchases to manage inventory
U.S.	\$24	\$104	
Europe	\$4	\$7	
New Hospitals Adds	90	425	Cash balance at Dec. 31, 2019 ~ \$464 million

297. On January 30, 2020, a *Seeking Alpha* article titled "Portola: Doubtful Trials and Falling Sales Make Andexxa An Unlikely Blockbuster" was published in response to the Company's "underwhelming" fourth quarter Andexxa sales.⁶¹ The commentator noted that he had recommended Portola back in October 2019 believing Andexxa was a "blockbuster" drug. The commentator noted recently that there were "serious concerns raised around Andexxa's [pre-FDA approval] ANNEXA-4 trial results, and ***questions are being asked as to how a drug with a***

⁶¹ Ingham, *supra* note 2.

list price of \$27,500 can replace an existing treatment costing \$5,000 if it has not yet been proven to be more effective.” The commentator further stated, “Portola has published numerous pieces of research during 2019 supporting management’s claim that Andexxa is a best-in-class solution for treatment of Factor Xa related bleeds. Andexxa has been shown to reduce inpatient mortalities, whilst rival 4FPCC treatments have been shown to be less effective when treating Factor Xa related bleeds. As I will describe below however, *doubts have been cast about these results that are quite troubling and could prevent Andexxa from making it onto hospital formulary lists.*”

298. The *Seeking Alpha* article noted that although Andexxa is the only FDA drug approved treatment for Eliquis and Xarelto, the “[n]eurocritical note suggests within the day-to-day hospital setting *this distinction carries little merit*” because “neither the FDA nor the American Heart Association (‘AMA’) insist on the use of officially approved drugs. That decision is made exclusively and independently by a physician who is free to use either an approved drug, or an off-label drug as they see fit” and because neither “the American Society for Hematology, nor the American College of Cardiology have expressed any preference for Andexxa over PCC [*e.g.*, Kcentra]. Although the American College of Chest Physicians expresses a preference for Andexxa, if available, this is clarified in the note as a consensus statement rather than a guideline recommendation.” Further, the cost comparison with Kcentra was heavily in Kcentra’s favor: “the price of Andexxa at \$3,300 per 100mg vial. Dosage is either 900mg or 1,800mg depending on severity (or in case a second dose is required if patient relapses)—that’s either \$26,400, or \$59,400 per dose.” In current practice, the author continues, “Kcentra at recommended dosage for anti-Xa treatment is 50 units per kg, meaning, at a price ~\$1.41 per unit, it will cost only \$7,050 for a 50kg patient.” The author opined that “[e]ven in a

best case scenario management must consider dropping the price of the drug – the list price is simply too high, especially so due to the drug’s short half life and confusion over what the appropriate dosage might be.”

2. The Company’s Q4 and Full-Year 2019 Results (1) Reveal that Andexxa is Floundering and Portola is Forced to Focus Like A “Laser” on it by Streamlining Organizationally and Discontinuing the Already Anemically-Used Bevyxxa and (2) Provide Disappointing Utilization Guidance Going Forward

299. After the close of market on February 26, 2020, Portola announced its financial results for the fourth quarter and full year 2019 in a press release (“Feb. 26, 2020 Press Release”) and held a conference call, the Feb. 26, 2020 Conference Call, that revealed in more detail the serious problems with customers’ adoption of the Andexxa drug and further reinforced investors’ concerns after the Company’s pre-announcement of financial results the previous month. Specifically, Portola reported in the Feb. 26, 2020 Press Release that it had sustained a fourth-quarter loss of \$96.7 million, or a loss of \$1.24 per share. Portola disclosed that its outsized loss for the quarter encompassed a \$27.5 million charge, which it attributed to inventory and manufacturing write-offs in line with its decision to discontinue operations related to the Bevyxxa.⁶² *Id.* In its press release, the Company explained that its internal restructuring, including the discontinuation of hibernated Bevyxxa (it had been limited to 10 hospitals after its catastrophic launch in May 2018), was necessary in order “to align resources to drive Andexxa growth.”

300. During the conference call, Garland admitted that the Company was “disappointed” with Andexxa’s performance in the fourth quarter,” as it saw “variability” in its business operations:

⁶² *Id.*

This all contributed to full year global net revenues for Andexxa of \$111.5 million. We exited the year with 640 hospitals that ordered Andexxa in the United States and together treated over 4,000 patients during the year. We remain excited about our long-term growth opportunity and look forward to building on our progress in 2020. ***While we are disappointed with the results in the fourth quarter, we gained important insights into the potential variability of our business and the impact that it can have at this stage of our launch.*** We are confident that Andexxa will continue to grow in 2020 and beyond. ***And it is our goal to provide annual revenue guidance once we have more visibility into these growth trends.***

301. In an effort to assuage investors' concerns over the future of Andexxa, Garland outlined "important steps" the Company was taking to "realign attention and resource allocation towards expanding the Andexxa customer base, driving utilization and increasing market share," including that the Company was forced to cease already-anemic Bevyxxa commercialization efforts at just 10 hospitals and undertake an internal restructuring:

[W]e are laser focused on driving near-term revenue growth. To support this strategy, we have taken three important steps to ***realign attention and resource allocation towards expanding the Andexxa customer base, driving utilization and increasing market share.***

First, we have completed an internal restructuring that aligns with our strategic plans to support Andexxa and Ondexxya [the international version of Andexxa]. We are streamlining our efforts and reducing spend on early stage and development programs in order to focus our resources on the Andexxa revenue drivers and lifecycle management.

Second, we made a strategic decision to discontinue our efforts to commercialize our partner, Bevyxxa. And finally, we've have made the decision not to initiate the CELTIC-1 trial for our SYK/JAK inhibitor, cerdulatinib[,] until 'we are able to secure a partner.

The company will focus on the foundation of our business, which is to fuel the near term and future growth of Andexxa and drive shareholder value by working towards our vision to be best-in-class in the treatment of serious blood related disorders

302. Also, during the Feb. 26, 2020 Conference Call, Koenig stated:

In 2019, we added 425 new hospital customers for a total of 640 accounts that have ordered Andexxa.... As we progress in 2020, we expect to add approximately 350 new hospital accounts throughout the year. We expect that

our new customer mix in 2020 will include hospitals in all tiers, as well as non-target hospitals that are proactively interested in adopting Andexxa, oftentimes through an affiliation with the larger hospital that is already using Andexxa.

303. During the Feb. 26, 2020 Conference Call, analysts repeatedly pressed the Company for more insight on Andexxa Q1 utilization trends, but Company refused to provide this insight:

Vikram Purohit - Morgan Stanley: Two from my side. Both kind of focused on the utilization reviews that you alluded to when you pre-announced 4Q '19 sales. So first off, *I wanted to see if you have any visibility into how utilization is trended into Tier 1 centers that were reported to have been stated DURs in 4Q'19?* And then, secondly, to the extent you have visibility on the topic. Do you have any additional centers year-to-date 2020 that have been stated similar DURs?

Garland: Thanks for the question, Vikram. So the focus of the call today is on Q4 and year-end. We look forward to giving you an update on both revenue and trends for Q1. And that's pretty much in line with our practice, which is to stick with the quarter when we're talking about the quarter call. But as it relates to drug utilization, DURs, for 2019, I'll turn that over to Sheldon, if you could provide some additional color?

Koenig: Thanks, Scott. Hi, Vikram. Thanks for the question. So as it relates to fourth quarter, not too much more additional that we have not already stated when we [were] at J.P. Morgan. But just a few things I do want to add. And that is I may reinforce it, as we talked about the drug utilization reviews, when we did our pre-announce, first, again, institutions are always going to conduct drug utilization reviews. This was common among all hospital products and not just Andexxa. And these can happen on a daily basis or weekly basis or monthly basis. I think for us, though the opportunity that exists is we can, as these DURs continue, we can actually help institution[s] better inform their decisions as you heard Rajiv mentioned. We have new data that will be coming out of ACC. 'That's truly going to point to the value proposition of Andexxa and we'll be able to utilize that data as we move forward through 2020 as institutions evaluate and perform drug utilization reviews

John McNeil - Goldman Sachs Group Inc.: I maybe wanted to start by, *given that we're more than halfway through 1Q '20, if you could provide any feedback and maybe what you've seen Andexxa trending like so far?* ...

Garland: Sure, John. As I said, I think the question that Vikram asked at the beginning, as is our standard practice, *we don't comment on a quarter until the*

quarter is done. This call is about Q4 and year-end. We do look forward to providing you an update in – on our Q1 progress. And that would be on our May call.

304. With regard to Portola’s bald claim that drug utilization reviews (*i.e.*, P&T Committee reviews) somehow curtailed revenue, Koenig acknowledged his comments at Gen 2 launch about that process: “[A]s we talked about the drug utilization reviews [(*i.e.*, P&T Committee reviews)], when we did our pre-announce, first again, institutions are always going to conduct drug utilization reviews. This was common among all hospital products and not just Andexxa.” Despite that comment, Koenig did not, with his comment, acknowledge in any way that he and Garland had *previously stated in Q1 2019 that a majority of hospital accounts had already conducted such reviews*, nor did he acknowledge why reviews would curtail usage at this time in Q4 2019.

305. On this news, the Company’s share price fell \$2.35 to close at \$10.17 per share on February 27, 2020, an approximately 19% decline on heavy trading volume. Meanwhile, the Nasdaq Composite Index and the Nasdaq Biotech Index decreased 4.61% and 4.13% respectively, on February 27, 2020.

306. As *Bloomberg* noted in a February 26, 2020 report, the Q4 2019 loss of \$96.7 million that the Company reported on February 26, 2020 was “wider than [the average analyst] estimate” of \$0.88 per share.

307. Moreover, while analysts had lowered their expectations for Andexxa after the Company’s January 2020 pre-announcement, management’s refusal to provide any additional insight on Andexxa utilization trends during the Feb. 26, 2020 Conference Call was cause for even further alarm over the drug’s true prospects.

308. For example, in its February 26, 2020 analyst report, Credit Suisse noted: “All About the Long-Term Opportunity for Andexxa. Management didn’t provide any additional

commentary on *Andexxa utilization trends in the beginning of 2020, the main area of investor focus following the Q4 revenue pre-announcement* that showed declining QoQ revenue. Instead, the earnings call focused on PTLA's strategy to capitalize on the LT opportunity for Andexxa/Ondexxa – the company is deprioritizing Bevyxxa and has postponed cerdulatinib's CELTIC-1 study pending partnership for the asset. ... In 2020, PTLA expects to add approximately 350 new hospital accounts, with a mix that will include hospitals in all tiers and non-target hospitals ... *this could drive the average revenue per account down slightly depending on reordering rates for existing accounts. ... With limited visibility in the near-term drug utilization trends, and potential choppiness in ordering patterns, we continue to expect the stock to be volatile around earnings for the next few quarters until a clearer picture of the drug's utilization pattern emerges.*" Credit Suisse cut its target price for Portola stock further from its cut in January 2020.

309. Likewise, Cowen issued a report on February 26, 2020 stating, "On tonight's call, Portola indicated that it expects to add approximately 350 ... new hospital accounts during 2020, implying a *deceleration* from the 425 hospitals added in 2019." Cowen decreased its 2020 and 2021 Andexxa estimates and further cut its Portola target price from its January 2020 price cut.

310. In its February 28, 2020 report, Morgan Stanley reported that "PTLA has faced significant pressure following 4Q19 earnings, which we suspect is likely related to (a) *the lack of annual Andexxa sales guidance* that some investors may have been expecting and (b) *little additional visibility* into the utilization reviews that impacted 4Q19 Andexxa sales, as cited in the company's pre-announcement of 4Q19 sales in January. We would expect *continued scrutiny of quarterly Andexxa performance* until mgt. is able to provide sales guidance. We

await mgt. commentary on the impact of recently instated initiatives to drive Andexxa growth, Ondexxa progress in the EU, and updates on partnership discussions for cerdulatinib.”

3. Portola Admits that the Marketing of Andexxa and Resistance to Utilization by Hospital Formulary Committees Was Adversely Impacted by Competition with Off-Label Use of 4F-PCCs

311. On February 28, 2020, after the market closed, Portola filed its FY 2019 Form 10-K. The Company added critical new language to its risk disclosures that highlighted that Portola’s “ability to grow our company is critically dependent upon the commercial success of Andexxa” that did not appear in prior SEC filings, effectively admitting that Andexxa had been encountering material difficulties in selling Andexxa in 2019 due to competition from “widely used” 4F-PCCs, a common standard of care preceding Andexxa and potential inadequacies in the initial studies relied upon to obtain FDA approval of Andexxa through the Accelerated Approval process. The new language provides:

We obtained regulatory approval of Andexxa [in 2018] in the United States through an Accelerated Approval process and in the EU under a conditional approval. The data supporting these approvals may limit our ability to market Andexxa. Continued approval may also be contingent upon the results of ongoing patient studies to demonstrate an improvement in hemostasis.

The Accelerated Approval regulations allow drugs that are being developed to treat an unmet medical need to be approved substantially based on evidence of an effect on a biomarker endpoint that is considered reasonably likely to predict clinical benefit rather than a clinical endpoint such as survival or irreversible morbidity. Our approval of Andexxa was supported by data from two Phase 3 ANNEXA studies (ANNEXA-R and ANNEXA-A), which evaluated the safety and efficacy of Andexxa in reversing the anticoagulant activity of the Factor Xa inhibitors rivaroxaban and apixaban in healthy volunteers, and interim patient data from our ongoing ANNEXA-4 single-arm, open-label study in patients on a Factor Xa inhibitor experiencing a life threatening or uncontrolled bleeding episode.

For example, we do not have comparator arm data, including clinical head to head data against the treatment options which were used by hospitals prior to the availability of Andexxa, which we believe continue to be widely used, including off-label use of 4F-PCCs and other coagulation factors. In addition, the efficacy statements in our product label are limited as the result of our single-arm, open-

label study. *These limitations have a significant impact on our ability to market Andexxa and establish it as the standard of care*, as pharmaceutical companies are generally prohibited from making product claims not set forth in their product labels. *These limitations can also increase resistance to utilization by hospital formulary committees and may also negatively impact government pricing discussions in the EU and abroad.*

312. The language from the FY 2019 Form 10-K cited in ¶311, above, is a rigorous reworking and supplementation of a prior disclosure seen, for example, in the 3Q 2019 Form 10-Q, filed on November 5, 2019. The language in that disclosure references “inherent limitations” of the studies but does not provide the critical examples of what those limitations are, including the disclosure that 4F-PCCs such as Kcentra continued to be widely used and the deficiencies in the original ANDEXXA-4 study.

313. Further, in the FY 2019 Form 10-K, Ernst & Young LLP (the Company’s auditor since 2004) communicated a “Critical Audit Matter” to the Board concerning Portola’s accounting for reserves on product revenue:

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments....

Reserves for returns on product revenue

Description of the Matter

As described in Note 3 to the consolidated financial statements, the Company had product revenue of \$111.6 million for the year ended December 31, 2019, which was net of \$20.6 million recorded as a reduction in revenue, which includes estimates of variable consideration for which reserves are established, including reserves for product returns.

Auditing the Company’s measurement of reserves for product returns under its contracts with customers was especially challenging because (1) the calculation involves subjective management assumptions about inventory remaining in the distribution channel as of the balance sheet date (i.e., units held by hospitals) that

could be subject to return in future periods under the Company's returns policy, and (2) the Company has limited commercial sales history on which to base its assumptions.

4. The Alexion Acquisition

314. Less than three months following the end of the Class Period, on May 5, 2020, Alexion Pharmaceuticals, a Delaware corporation ("Alexion" or "Parent"), and Portola issued a joint press release announcing the execution of an Agreement and Plan of Merger ("Merger Agreement") by and among Alexion as Parent, Odyssey Merger Sub, Inc. ("Odyssey") as purchaser, a direct wholly-owned subsidiary of Alexion, and Portola relating to a planned tender offer ("TO") of all of the outstanding shares and common stock of Portola (the "Merger Announcement").⁶³

315. On May 27, 2020, Alexion together with Odyssey filed its tender offer statement on Schedule T/O. Alexion offered to purchase the shares of Portola at \$18.00 per share net to the holder of each such share. This \$18 per share price was a 231.96% premium over the May 4, 2020 price of \$7.76 (the day before the Merger Announcement), but far lower than the trading prices between the Class Period start and the last trading date before the first partial disclosure, which ranged from \$22.18 to \$37.26.

⁶³ The Merger Documents include the following documents, among others: (i) Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) ("Pre-Commencement Communications"), filed with the SEC on May 5, 2020 and May 7, 2020; (ii) Tender Offer Statement under Section 14(d)(1) of the Exchange Act (Schedule TO) ("Tender Offer Statement"), filed with the SEC on May 5, 2020, May 6, 2020, May 7, 2020, and May 27, 2020 (and Amendments 1 thru 6 thereto, filed with the SEC between June 1, 2020 and July 2, 2020); and (iii) Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities Act (Schedule 14D-9) ("Schedule 14D-9"), filed with the SEC on May 5, 2020, May 7, 2020, May 26, 2020, and May 27, 2020 (and Amendments 1 thru 6 thereto, filed with the SEC between June 1, 2020 and July 2, 2020).

VI. EXCHANGE ACT VIOLATIONS

A. Defendants' Material Misrepresentations

316. Throughout the Class Period, Defendants repeatedly issued false and misleading statements that there was strong demand for Andexxa and that Andexxa was being broadly utilized by hospitals. To further this deceit, the Company employed bogus metrics such as “new hospital additions” and “reorder rate,” which the Company claimed showed that there was strong demand for Andexxa when in fact they did not have strong demand. The Company further omitted substantial negative information concerning Andexxa, which it was under a duty to disclose when it made these false and misleading statements.

317. During the Class Period, Defendants also issued several categories of materially false and misleading statements regarding Company's compliance with GAAP and its internal Revenue Recognition Policy, its net revenue figures, and internal controls described in Garland's and Dier's SOX Certifications. These statements were false and misleading because the Company recognized revenue upon sell in to its distributors without sufficient relevant historical sales and return data with which to conclude that it was “probable” that there would not be a significant reversal in the amount of reversal due to returns, in violation of ASC 606.

1. Defendants Issued False and Misleading Statements Falsely Portraying the Commercial Launch of Andexxa as a Success

a. Defendants Made False and Misleading Statements Concerning Andexxa Demand

318. Throughout the Class Period, Defendants created a false impression of the state of affairs at the Company. Defendants repeatedly reassured investors that Andexxa demand was “strong and growing” and that the growth was on a “linear” trajectory, and that, as a result, the Company had “strong execution” on the Andexxa commercial launch. These statements were false. However, even if some are argued to be literally true – and they are not – the context

and manner of their presentation make them false and misleading statements that do not have the ability to inform, but instead mislead, investors.

319. The following are a series of false and misleading statements that Andexxa demand was strong and growing and that growth was on a linear trajectory:⁶⁴

- “***Andexxa Demand is Strong and Growing.***” (Jan. 8, 2019 Presentation.)
- Garland stated that the Company “expected that the ***current trajectory should continue at a linear rate***” with respect to revenues. (Garland, May 8, 2019 Conference Call.)
- That “enthusiasm and the desire from what we might call a nontarget hospital to stock this drug,” which therefore “speaks both to the ***significant value of the drug as well as the desire to use the product as quickly as possible.***” (Garland, May 8, 2019 Conference Call.)
- That “our first quarter results continue to ***reflect strong demand*** for Andexxa, as well as focused execution on our commercial launch.” (May 8, 2019 Press Release.)
- “This is our third consecutive quarter of strong revenues for Andexxa and ***reflects solid demand.***” (Garland, Mar. 1, 2019 Conference Call.)
- “Andexxa ***Demand in the U.S. is Strong and Growing.***” (May 8, 2019 Presentation.)
- “I think we’ve mentioned that we think ***it’s a linear rate***, which obviously [is] going to be some variability over time.” (Garland, May 8, 2019 Conference Call.)
- That “***daily demand continue[s] to grow.***” (Koenig, May 8, 2019 Conference Call.)
- “So the review as it relates to [P&T] committees booking at the product regardless of that whether it’s Gen 1 or Gen 2 is technically a six to nine month process And this is certain industry norms. And you go I know we get questions about sort of rate of hospital uptake and one of the things we’ve said all along is that ***we expect that rate to continue at a pretty***

⁶⁴ **Bolded** and *italicized* quoted statements are alleged to be false and misleading, while other statements are provided for context.

linear rates to exactly *what we're saying and totally in line with our expectations.*" (Koenig, May 8, 2019 Conference Call.)

- "This is our fifth consecutive quarter of strong revenue growth reflecting our exceptional launch execution and *continued demand for Andexxa.*" (Aug. 7, 2019 Press Release.)
- "*Andexxa Demand in the U.S. is Strong and Growing.*" (Aug. 7, 2019 Presentation.)
- "*There is continued strength and demand for Andexxa....*" (Garland, Aug. 7, 2019 Conference Call.)
- "Our second quarter results reflect the fifth consecutive quarter of strong launch, execution and *growing demand for Andexxa.*" (Dier, Aug. 7, 2019 Conference Call.)
- That it "*feel[s] like there's a lot of momentum, wind in our sales* for Portola. We announced on our quarterly call \$27.1 million in net revenues for Andexxa. That was our fifth consecutive quarter of strong revenue growth and also expectation-beating revenues. So very solid there." (Garland, Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call.)
- "In Q3, we delivered *strong Andexxa revenue growth* in the United States ... our team's *strong execution on the launch* of Andexxa in the United States." (Garland, Nov. 5, 2019 Conference Call.)
- "Our performance in the third quarter is a testament to the strong growth since launch and *long-term potential of our business.*" (Koenig, Nov. 5, 2019 Conference Call.)
- "Our financial results reflect *strong growth of Andexxa in the U.S. and an initial demand* in Europe." (Dier, Nov. 5, 2019 Conference Call.)
- "*Andexxa Demand is Strong and Growing.*" (Nov. 5, 2019 Presentation.)

320. The bolded and italicized statements in ¶319, that the Company was experiencing strong demand and linear growth were affirmative statements of present fact that were materially false and misleading when made because the Company was in fact facing substantial obstacles and significant negative feedback from hospitals in marketing Andexxa during the Class Period, suggesting neither strong ongoing demand nor linear growth.

321. The series of false and misleading statements identified in ¶319 are statements of fact and not forward looking statements. Rather, referencing such things as current “demand” and current “trajectory,” they are informed by past information, current understanding, and current knowledge of what is expected in the future. Further, Defendants knew at the time they made their statements that demand and utilization trends were not expected to continue as they were suggesting, making them false and misleading present statements of fact. Finally, even if they are considered to contain forward looking statements – and they do not – they would be statements containing a mixture of past, current, and forward looking facts, making them actionable.

322. The truth that demand was neither strong and robust nor growing at a trajectory or rate that Defendants stated and otherwise implied is evidenced by the following consistent statements by former employees of Portola:

- a. statements by CW1 that (i) hospitals had difficulty justifying the high cost of Andexxa and that they could rely on other treatments that they had been using for years without spending as much; (ii) the data concerning the effectiveness of Andexxa did not justify the cost versus the benefit; (iii) some hospitals were carrying Andexxa as a “CYA” and did not intend to use it; and (iv) because of price, a hospital covered by CW1 had very restrictive use protocols in place limiting Andexxa’s use to life-threatening intracranial bleeds (*e.g.*, ¶¶106-07);
- b. statements by CW3 that (i) sales of Andexxa were stagnant throughout his/her time at Portola selling the drug; (ii) Andexxa’s price was problematic, “[i]t was a struggle for [him/her] from day one to sell

Andexxa,” and “the hospital pharmacists were terrified of [Andexxa] and not from a clinical point[, but] strictly from a cost point”; (iii) small, rural hospitals that CW3 called on believed that Andexxa was priced “way too aggressively” and many could not afford it; (iv) a hospital with 100 beds or less would have to make a choice between purchasing Andexxa and hiring a staff member because of the high cost; (v) Kcentra, another anticoagulant reversal drug, was a cheaper alternative to Andexxa for many hospitals; and (vi) a professor of pharmacology and clinical specialist paid to speak on the benefits of Andexxa by Portola at a June 2018 Hospital Pharmacy Society conference that was attended by 55 hospital pharmacists stated that he would nonetheless use Kcentra over Andexxa because of its cost (*e.g.*, ¶¶118-20, 122-23);

- c. statements by CW4 that (i) sales of Andexxa were slow throughout the time that s/he worked at Portola and sold Andexxa; (ii) hospital pharmacists were shocked at the price difference between Kcentra and Andexxa; (iii) s/he believed that hospitals were initially worried about being sued if a patient died following a severe bleed and the particular hospital did not carry Andexxa, but an article written by three pharmacists in 2019 provided hospital pharmacy directors with information to push back on ordering Andexxa; (iv) many hospitals used the publication of the article to further bolster their position that Andexxa was too expensive to carry when a cheaper alternative such as Kcentra was available; and

(iv) the high cost of Andexxa put a strain on pharmacy budgets (*e.g.*, ¶¶126, 127, 129, 131);

- d. statements by CW5 that (i) from his/her perspective, the biggest issues Portola had concerning Andexxa usage was the cost of the drug combined with the off-label use of Kcentra; (ii) Andexxa was very expensive and sales stayed at a consistent level until there was a decline; (iii) through his/her own observations and communications with other sales reps, the rate of sales of Andexxa were not increasing during 2019 throughout the Class Period; (iv) pharmacies made the purchasing decisions, and they told doctors who wanted Andexxa that the drug was not available or that its use was restricted and that Kcentra was the only available treatment on the formulary; (v) while sales numbers were steady, some hospitals stocked up but did little reordering; (vi) s/he heard from other sales reps that beginning in the second half of 2019, there was an increase in the volume of returns, which s/he described as a large amount of returns of Andexxa; (vii) he/she believes that hospitals made a cost versus utilization analysis and determined that it was too costly to stock more than 3 to 5 boxes of Andexxa or to reorder additional boxes given that the indications were so limited; and (viii) insurance coverage does not affect a hospital pharmacy department's decision about whether to purchase Andexxa because third-party reimbursement tends to go back to the general hospital accounts and generally does not get refunded to the pharmacy department's budget (*e.g.*, ¶¶137-39, 142-43, 146);

- e. statements by CW6 that (i) many hospitals refused to add Andexxa to their formularies because of its high price, telling him/her that they have learned to manage bleeding with these patients and that they have strategies that have been working so they wouldn't purchase at the current price; (ii) "[a]s soon as the customers saw the price, they said that they have lived without it for five or six years and that they could live without it longer"; (iii) two Level I large bed trauma center hospitals in his/her district pushed back on the pricing of Andexxa and placed restrictions on who could use the drug; (iv) 90% of his/her customer calls responded with a "flat-out 'no;'" and (v) Portola was "absolutely" struggling to sell Andexxa in the period leading up to its August 2019 Offering (*e.g.*, ¶¶148-51, 154, 157); and
- f. statements by CW12 that (i) working in the San Francisco headquarters, s/he was aware that the sales of Andexxa were not going well via "lunchroom" conversation with people in the Sales Division; and (ii) s/he believes that, in the Spring of 2019, sales had "come down," based on lunchroom conversations with sales staff, who were asking why sales were not going well (*e.g.*, ¶¶197, 199).

323. The truth that demand was neither strong and robust nor growing at a trajectory or rate that Defendants stated and otherwise implied is further evidenced by the following statements by customers or potential customers who were marketed Andexxa by Portola:

- a. statements by CW7 that (i) s/he presented Andexxa to the P&T Committee, and it was felt that the data presented in the clinical trial was

“flimsy;” (ii) nonetheless, the hospital felt that it was irresponsible to not carry the drug while prescribing Xarelto or Eliquis; it restricted use to only life-threatening intercranial bleeding for patients being treated with Xarelto or Eliquis, which s/he understands is consistent with how hospitals throughout the country are utilizing Andexxa; (iii) the hospital system only stocks one high dose and one low dose of Andexxa because the usage is so limited, where the system only authorizes Andexxa’s use for intercranial bleeding, which is normally accompanied by a stroke; (iv) in his/her hospital system, restrictions were based on effectiveness and not price; (v) it is not that Andexxa is ineffective, but it is only appropriate for certain indications and is not a “miracle drug;”; (vi) the data on the use of Kcentra was as effective in many of the same situations as Andexxa; and (vii) it is his/her understanding that his/her hospital’s practices are consistent with how hospitals throughout the country are utilizing Andexxa (*e.g.*, ¶¶162-64, 166-67);

- b. statements by CW8 that (i) his/her hospital system has Andexxa on its formulary but restricts its usage to only life-threatening events involving intercranial bleeding; (ii) the decision to restrict Andexxa’s use is based on the cost versus benefit and the data presented in Portola’s clinical trials; (iii) treatments such as Kcentra and Feiba have been used in the past and have been shown to be effective for less cost; (iv) throughout the entire hospital system, Andexxa has been used less than half a dozen times; (v) the data supporting use of Andexxa for GI bleeding was not enough to

support its use for that type of bleed; (vi) Portola conducted an additional study of Andexxa, the results of which were presented at the American Society of Hospital Pharmacists convention in December 2019 in Las Vegas, Nevada and, in his/her opinion, the study was weak and still not convincing enough to change the Andexxa restrictions; and (vii) s/he believes that most hospitals have similar restrictions on Andexxa (*e.g.*, ¶¶171, 173-75);

- c. statements by CW9 that (i) his/her team determined that the cost of Andexxa was too high when the benefits are compared with other medications, including PCC treatments such as Kcentra and Feiba, which were effective for significantly less cost; (ii) most hospitals in his/her hospital's peer group have made the same determination concerning Andexxa—that it is too costly when compared with other treatments; (iii) it is possible that, by carrying Andexxa, a hospital pharmacy may be unable to hire a technician or otherwise fill a vacant position; and (iv) Andexxa is a drug that would come out of the hospital pharmacy's budget (and third-party reimbursements do not affect the cost to the pharmacy department) (*e.g.*, ¶¶179, 181-83);
- d. statements by CW10 that (i) his/her hospital determined that the cost of Andexxa was too prohibitive to carry and that there was no justification for Andexxa's pricing when they could try other things; (ii) if they had a patient that was critical and needed Andexxa, then the patient should be immediately transferred by ambulance to a larger hospital within the area

that carried Andexxa; and (iii) the hospital's CCO said that other drugs that were cheaper than Andexxa, such as Kcentra, could be used (*e.g.*, ¶¶188-89);

- e. statements by CW11 that (i) high cost is why Andexxa was kept off the hospital's formulary, where the hospital had a cheaper, reasonable alternative in Feiba; (ii) both a 2018 P&T Committee review of Andexxa as well as a review by medical staff informed and supported that position; and (iii) s/he believes that many other hospitals in his/her state made a similar choice as his/her facility to not add Andexxa to their formularies (*e.g.*, ¶¶191-93); and
- f. statements by CW13 that (i) his/her hospital limits the use of Andexxa to intracranial bleeds due to cost; (ii) his/her hospital carries it for fear of liability; and (iii) that s/he believes other hospitals in his/her region that accept critical patients from his/her hospital do not carry Andexxa due to cost (*e.g.*, ¶¶203-05).

324. The truth that demand was neither strong and robust nor growing at a trajectory or rate that Defendants stated and otherwise implied is further evidenced by the evasive responses by senior management to analyst questions during quarterly conference calls. For example, Garland downplayed whether 4F-PCCs and other pre-Andexxa treatments were being chosen over Andexxa on the Mar. 1, 2019 Conference Call, Garland said that the Company was seeing no issues concerning utilization on the Aug. 7, 2019 Conference Call (right before the August 2019 Offering), and Garland side-stepped a question regarding historical utilization at hospitals

that had been stocking Andexxa for over the past year during the November 5, 2019 Conference Call:

- a. **[Analyst]:** ... where Andexxa is available, is it your understanding that that is clearly the first line therapy for the Xa bleeds or might there be some hospitals that while they have Andexxa available, are still using some of the older methods like fresh frozen plasma or four-factor PCCs even though that Andexxa is available?

[Garland]: Certainly, we know hospitals are using PCCs and we expect they probably will continue to use PCCs although we believe that's inappropriate given the fact that we're the only approved agent. But in many ways you call it, it really does vary by hospital. *It's kind of hard to speak about it generally because each hospital is somewhat unique.* (§227);

- b. **[Analyst]:** Does it concern among investors that over time as you get later doctors to stock a drug, their utilization is going to be less than the people who have stocked already. So the revenue curve is going to—going to begin to plateau or decelerate. What are your—what are your thoughts on that concern that's in the market.

[Garland]: What we are seeing is we've looked at a cohort of our institutions, large important institutions that came on earlier at E[S]P and actually what we're seeing is increased usage over time or deepening usage over time. *There's nothing that we're seeing today that makes us concerned about a lack of pull through or plateauing of our utilization.* (§257); and

- c. **“[Analyst]:** I'm just wondering if you could start to give ... some kind of on a comparison or, if it's high level even about the current utilization at some of those hospitals that have been online for at least a year maybe even over a year versus maybe some that have come online in the past six month....

[Garland]: [N]ow that we've got a couple of years under—or a year under our belt how does the utilization look[?] We aren't giving any detailed information around utilization per hospital per month. *What we have seen is that, that utilization per hospital per month stays—has been staying consistent in 2019.”* (§273).

325. Similarly, when asked by an analyst on the May 8, 2019 Conference Call to comment on timelines to go through “the hospital protocol review for Gen 2 relative to Gen 1,”

Koenig started by acknowledging a 6 to 9 month process while also assuring that “we expect that rate to continue at a pretty linear rates to exactly what we’re saying and ***totally in line with our expectations.***” (¶242.) Garland on the same call also assured investors that the majority of the P&T efforts were in the past for the 300 hospital accounts acquired at that time: “***The majority of hospitals have made P&T decisions. And so the majority of them have the product on the protocol and are using the product....***” (¶243.)

326. The truth that demand was neither strong and robust nor growing at a trajectory or rate that Defendants stated and otherwise implied is further evidenced by the actions of senior management during the Class Period to promote additional data to support the use of Andexxa over 4F-PCCs. Before and during the Class Period, CWs repeatedly communicated to senior management that Andexxa was having difficulty competing with 4F-PCCs because of cost and concerns regarding the efficacy of Andexxa (¶¶108, 154-56). The content of the following releases touting Andexxa over 4F-PCCs coupled with the timing of these releases shows that Defendants knew that 4F-PCCs were a significant threat to Andexxa’s launch but concealed such information from investors:

- a. On July 8, 2019, Portola announced new *in vitro* data establishing the relationship between concentrations of the direct oral anticoagulants apixaban and rivaroxaban and the ability of 4F-PCC to correct inhibition of thrombin generation, compared with warfarin anticoagulation reversal by 4F-PCC. (¶251.)
- b. On November 15, 2019, Portola issued a press release announcing that Annals of Emergency Medicine, the journal of ACEP, published a multidisciplinary anticoagulant reversal and replacement guidance

statement. In the guidance statement, ACEP highlighted Andexxa as a first-in-line, FDA approved reversal agent for patients treated with apixaban or rivaroxaban, “as compared to 4F-PCC, which are highlighted as a second-in-line option for Factor Xa reversal and recommended for use only if Andexxa is not available.” (§281.)

327. The previously referenced actions by senior management during the Class Period of promoting additional data to support the use of Andexxa over 4F-PCCs demonstrates that demand is not strong and growing when viewed in light of (i) the timing of the studies, (ii) comments by a CW, and (iii) an article published in *Seeking Alpha* on January 30, 2020 calling this additional Portola data into doubt:

- a. This data was pushed out only after Portola stopped relying on “reorder rate” (§268) and refused to answer specific questions about historical trends regarding demand and utilization during the November 5, 2019 analyst call (§273), and as the Company neared the end of the Class Period and the point when the truth about demand and revenue was going to emerge.
- b. CW8 stated that Portola conducted an additional study of Andexxa which was presented at the American Society of Hospital Pharmacist convention in December 2019 in Las Vegas, Nevada which, in his/her opinion, was weak and still not convincing enough to change the Andexxa restrictions. (§175.)
- c. On January 30, 2020, *Seeking Alpha* published a report authored by Edmund Ingham entitled: “Portola: Doubtful Trials And Falling Sales

Make Andexxa An Unlikely Blockbuster.” Ingham discussed data Portola had published in 2019 claiming to support Andexxa as “best-in-class.” “Finally, Portola has published numerous pieces of research during 2019 supporting management’s claim that Andexxa is a best-in-class solution for treatment of Factor Xa related bleeds. ... As I will describe below however, *doubts have been cast about these results that are quite troubling and could prevent Andexxa from making it onto hospital formulary lists.*” (¶297.)

328. The truth that demand was neither strong and robust nor growing at a trajectory or rate that Defendants stated and otherwise implied is further evidenced by the following:

- a. the Company’s ultimate admissions on January 9, 2020 that the Portola encountered “[f]at quarter over quarter demand due to a decrease in utilization, primarily in tier 1 accounts” and that in certain of these accounts, hospital pharmacies curtailed use of Andexxa following drug utilization reviews in an effort to manage pharmacy budgets” (¶282);
- b. the Company’s admissions on January 14, 2020 that Andexxa sales had fallen because of “lower distributor purchases to manage inventory” in order “to keep their inventory levels at a constant level in the fourth quarter” (¶¶295-96);
- c. the Company’s acknowledgement on February 26, 2020 that the Company was “laser focused on driving near-term revenue growth [for Andexxa]” and was taking three important steps to “realign attention and resource allocation towards expanding the Andexxa customer base, driving

utilization and increasing market share,” including the discontinuation of the limited remaining Bevyxxa operations (§§301);

- d. the Company’s admission in its FY 2019 Form 10-K filed on February 28, 2020 that it knew since Andexxa was approved by the FDA in early 2018 via the Accelerated Approval Program that the ANDEXXA-4 study proffered and relied upon had “inherent limitations” that could impact the viability of Andexxa, where, for example, the Company was having significant difficulties competing with the off-label use of 4F-PCCs and other coagulation factors given a lack of comparative data and that hospital formulary committees were resistant to utilizing Andexxa because the Company lacked a clinical trial data comparing it to treatments used before Andexxa’s FDA approval (§§311-12); and
- e. Defendants lacked sufficient relevant historical evidence and other facts to recognize revenue upon sell-in, *i.e.*, upon shipment to its distributors under ASC 606. Thus, the revenue figures could not support these assertions of strong, growing or robust demand (*see* Section VI.A.2.).

329. These misstatements were material, non-puffery, because a reasonable investor would consider the fact that demand for Andexxa, Portola’s lead drug, was weaker than portrayed by the Company meant that Andexxa’s commercial launch was failing.

330. When considering the context in which these statements were offered, these misstatements were important to investors and analysts. Throughout the Class Period, Portola had disclosed as material in public filings the critical importance to the viability of Andexxa of creating and maintaining strong demand and utilization, as well as procuring a hospital’s

willingness to pay for Andexxa and to forgo use of cheaper, quasi-competitive 4PCC products, such as Kcentra. (¶¶96-99.) Portola made repeated statements about demand throughout the Class Period, despite evidence to the contrary. (*Id.*; e.g., ¶319.) Those statements were in that context materially misleading. Further, on the conference calls cited throughout, analysts repeatedly inquired directly into demand and factors meant to serve as indicators of demand, and misstatements made during those conference calls were materially false and misleading in that context as a result. (E.g., ¶¶227, 242, 253, 257, 272-74, 285, 303, 324.)

331. These statements about demand and its trajectory were fundamentally based on quantifiable metrics, which were capable of objective verification and consideration. Thus, statements about demand were not statements of optimism, but rather statements premised on facts.

332. In fact, analysts noted in reports throughout the Class Period that demand and utilization of Andexxa were factors driving the commercial success of the Company:

- “[W]e continue to see notable upside in Portola shares as the commercial expansion of Andexxa into additional hospitals drives revenue growth and label expansions into emergency surgery and enoxaparin reversal increase the total market opportunity.” (William Blair, Apr. 4, 2019.)
- “The next few quarters will be critical to see how the initial demand translates into orders and sales and the likelihood of the product being able to achieve the \$1.34Bn in peak global sales that we currently forecast.” (Credit Suisse, May 8, 2019.)
- “[M]anagement remains very encouraged by the launch and believes it is progressing better than expected based on analogues of other hospital launches from the past 30 years. The message remains that the relatively slow uptake should not be unexpected at the outset of a hospital launch, the US demand for Andexxa is strong and growing.” (Credit Suisse, June 27, 2019.)
- “We are encouraged by the continued growth of Andexxa, particularly with 74% of sales in the quarter coming from hospitals reordering Andexxa. In addition, management commentary continues to be positive, highlighting the increased utilization trends with current accounts, recent

increase in CMS NTAP reimbursement level (to 65% from 50%), access to the Veterans Administration health system, and first sales in Europe. We believe there is continued long[-]term momentum for Andexxa beyond the addition of new accounts over the next several quarters, including strong growth of the factor Xa class, label expansion to include urgent surgery and enoxaparin, and continued guidance recommendations including the recent Joint Commission updates.” (William Blair, Aug. 8, 2019.)

- “Andexxa is now available in roughly 550 hospitals in the United States, including another 125 new hospitals added in the quarter, and 76% of sales were from reorders as opposed to initial stocking (compared to 74% in the second quarter). We believe the continued uptake of Andexxa has been encouraging in both the United States and Europe, and continue to see a long-term opportunity for Andexxa through increasing penetration into a rapidly growing market.” (William Blair, Nov. 6, 2019.)

333. The significant stock drops on January 10, 2020, January 13, 2020, and February 27, 2020, which revealed the weak demand and utilization of Andexxa further demonstrate the materiality of these false and misleading statements. Further, analyst reports reacting to the news pointed specifically to issues of demand and utilization as factors both explaining the Company results and stock drops demonstrates the materiality of the false and misleading statements. (*E.g.*, ¶¶306-10.)

b. Defendants Made False and Misleading Statements Concerning Andexxa Utilization

334. Throughout the Class Period, Defendants repeatedly touted that Andexxa was being “broadly” and “deeply” utilized by hospitals. As a result, Andexxa was portrayed as becoming the standard of care as the treatment of life-threatening or uncontrolled bleeding in patients treated with rivaroxaban or apixaban. This portrayal further fed into the false theme that the Andexxa commercial launch was being strongly executed. These statements were false. However, even if some are argued to be literally true – and they are not – the context and manner of their presentation make them false and misleading statements that do not have the ability to inform, but instead mislead, investors.

335. The following are a series of false and misleading statements that Andexxa was being “deeply” utilized by hospitals:

- “[U]tilization on a per hospital level [] deepen[s] both as physicians get used to the product and as hospitals continue to go through their protocol development.” (Garland, May 8, 2019 Conference Call.)
- “I do know that when we spoke to customers about **Q4 utilization, the #1 reason was actually supply. That was probably the main reason why accounts did not order.**” (Garland, Jan. 8, 2019 Conference Call.)
- “The majority of hospitals have made P&T decisions. So the majority of them have the product on the protocol and **are using the product.**” (Koenig, May 8, 2019 Conference Call.)
- “So the review as it relates to [P&T] committees booking at the product regardless of that whether it’s Gen 1 or Gen 2 is technically a six to nine month process And this is certain industry norms. And ... one of the things we’ve said all along is that we expect that rate to continue at a pretty linear rates to exactly **what we’re saying and totally in line with our expectations.**” (Koenig, May 8, 2019 Conference Call.)
- “So everything that we’re seeing so far in terms of the launch kinetics points to a **deepening and a pull-through of utilization.**” (Garland, June 11, 2019 Goldman Sachs Global Healthcare Conference Call.)
- “Also last week, the Joint Commission known as JCAHO, the oldest and largest accrediting body for hospitals and med care [ph] issued a new report on DOACs. The report directs accredited hospitals and critical care centers to stock anecdotes appropriate for the use with each type of anticoagulant. **Reports like these are making it clear that Andexxa is becoming the standard of care for patients on apixaban or rivaroxaban.**” (Garland, Aug. 7, 2019 Conference Call.)
- “[W]hat we’re seeing is increased usage over time or deepening usage over time. **There’s nothing that we’re seeing today that makes us concerned about a lack of pull-through or a plateauing of our utilization.**” (Garland, Aug. 7, 2019 Conference Call.)
- “Adding new accounts is just one part of ensuring continued growth. The second component is **deepening utilization within existing accounts and we are seeing encouraging trends.**” (Koenig, Aug. 7, 2019 Conference Call.)
- “I will tell you we’re really happy with what we’re seeing both in terms of new account adds as well as **deepening [ph] of the utilization** and we’ll

certainly give you updates as we move forward.” (Garland, Aug. 7, 2019 Conference Call.)

- “[W]hat we’re seeing is increased usage over time or ***deepening usage over time.***” (Garland, Aug. 7, 2019 Conference Call.)
- “[W]hat we’re seeing is real ***pull-through at hospitals.***” (Garland, Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call.)
- “What we have seen is that, ***that utilization per hospital per month stays—has been staying consistent in 2019.*** That is with—in the context of us broadening the hospital-base to include more Tier 2 and Tier 3 accounts.” (Garland, Nov. 5, 2019 Conference Call.)

336. The following are a series of false and misleading statements that Andexxa was being “broadly” utilized by hospitals:

- Koenig also noted that the Company is “***seeing that the utilization of Andexxa is both ICH bleeds and also in other bleeds outside of ICH. So we’re seeing a mix of all types of bleeds that are currently being treated.***” (Koenig, May 8, 2019 Conference Call.)
- Garland noted the Company is “pleasantly surprised by the fact that the ***drug is being used broadly*** to the label obviously, but it’s definitely not being missed again a specific type bleed type like intracranial hemorrhage.” (Garland, May 8, 2019 Conference Call.)
- “[W]e’re actually seeing ***broad usage across all bleed types*** not necessarily focused on intracranial hemorrhage.” (Garland, May 8, 2019 Conference Call.)
- “Also last week, the Joint Commission known as JCAHO, the oldest and largest accrediting body for hospitals and med care [ph] issued a new report on DOACs. The report directs accredited hospitals and critical care centers to stock anecdotes appropriate for the use with each type of anticoagulant. ***Reports like these are making it clear that Andexxa is becoming the standard of care for patients on apixaban or rivaroxaban.***” (Garland, Aug. 7, 2019 Conference Call.)
- “[W]e are definitely ***seeing usage in patients outside of the intracranial hemorrhage space.***” (Garland, Aug. 7, 2019 Conference Call.)
- “[W]e’re seeing actually is ***broad utilization.*** We’re not seeing it niched to just intracranial hemorrhage.... But like I said, ***what we are seeing is usage broadly.***” (Garland, Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call.)

- ***“Andexxa is being used in all ranges of bleeds.*** So not only intracranial hemorrhage, but also GI bleeds, trauma related compartmental bleeds. So we’re seeing it being used across all bleed types.” (Koenig, Nov. 5, 2019 Conference Call.)

337. The bolded and italicized statements in ¶¶335-36, that Andexxa was experiencing “broad” and “deepening” utilization and usage were affirmative statements of present fact that were materially false and misleading when made because contrary to the Company’s statements Andexxa was encountering significant resistance from hospitals and their drug utilization review committees which placed severe restrictions on Andexxa usage when stocked because of the high cost coupled with limited clinical data and an available more cost-effective alternative.

338. The series of false and misleading statements identified in ¶¶335-36 are statements of fact and not forward looking statements. Rather, referencing such things as current utilization and utilization trends (both depth and breadth), they are informed by past information, current understanding, and current knowledge of what is expected in the future. Further, Defendants knew at the time they made their statements that demand and utilization trends were not expected to continue as they were suggesting, making them false and misleading present statements of fact. Finally, even if they are considered to contain forward looking statements – and they are not – they would be statements containing a mixture of past, current, and forward looking facts, making them actionable.

339. The truth that Andexxa was not “broadly” and “deeply” being utilized is evidenced by the following statements by former employees of Portola:

- statements by CW1 that (i) hospitals had difficulty justifying the high cost of Andexxa and that they could rely on other treatments that they had been using for years without spending as much; (ii) the data concerning the effectiveness of Andexxa did not justify the cost versus the benefit;

(iii) some hospitals were carrying Andexxa as a “CYA” and did not intend to use it; and (iv) because of price, a hospital covered by CW1 had very restrictive use protocols in place limiting Andexxa’s use to life-threatening intracranial bleeds (*e.g.*, ¶¶106-07);

b. statements by CW3 that (i) Andexxa’s price was problematic, “[i]t was a struggle for [him/her] from day one to sell Andexxa,” and “the hospital pharmacists were terrified of [Andexxa] and not from a clinical point[, but] strictly from a cost point”; (ii) small, rural hospitals that CW3 called on believed that Andexxa was priced “way too aggressively” and many could not afford it; (iii) a hospital with 100 beds or less would have to make a choice between purchasing Andexxa and hiring a staff member because of the high cost; (iv) Kcentra, another anticoagulant reversal drug, was a cheaper alternative to Andexxa for many hospitals; and (v) a professor of pharmacology and clinical specialist paid to speak on the benefits of Andexxa by Portola at a June 2018 Hospital Pharmacy Society conference that was attended by 55 hospital pharmacists stated that he would nonetheless use Kcentra over Andexxa because of its cost (*e.g.*, ¶¶118-20, 122-23);

c. statements by CW4 that (i) hospital pharmacists were shocked at the price difference between Kcentra and Andexxa; (ii) s/he believed that hospitals were initially worried about being sued if a patient died following a severe bleed and the particular hospital did not carry Andexxa, but an article written by three pharmacists in 2019 provided hospital pharmacy directors

with information to push back on ordering Andexxa; (iii) s/he believed that hospitals were initially worried about being sued if a patient died following a severe bleed and the particular hospital did not carry Andexxa, but an article written by three pharmacists in 2019 provided hospital pharmacy directors with information to push back on ordering Andexxa; (iv) many hospitals used the publication of the article to further bolster their position that Andexxa was too expensive to carry when a cheaper alternative such as Kcentra was available; and (iv) the high cost of Andexxa put a strain on pharmacy budgets (*e.g.*, ¶¶126, 127, 129, 131);

- d. statements by CW5 that (i) from his/her perspective, the biggest issues Portola had concerning Andexxa usage was the cost of the drug combined with the off-label use of Kcentra; (ii) pharmacies made the purchasing decisions, and they told doctors who wanted Andexxa that the drug was not available or that its use was restricted and that Kcentra was the only available treatment on the formulary; (iii) he/she believes that hospitals made a cost versus utilization analysis and determined that it was too costly to stock more than 3 to 5 boxes of Andexxa or to reorder additional boxes given that the indications were so limited; (iv) “all” of CW5’s accounts placed restrictions on the use of Andexxa due to its cost (and not due to the effectiveness of the drug); and (v) insurance coverage does not affect a hospital pharmacy department’s decision about whether to purchase Andexxa because third-party reimbursement tends to go back to

the general hospital accounts and generally does not get refunded to the pharmacy department's budget (*e.g.*, ¶¶137-39, 142-43, 146); and

- e. statements by CW6 that (i) many hospitals refused to add Andexxa to their formularies because of its high price, telling him/her that they have learned to manage bleeding with these patients and that they have strategies that have been working so they wouldn't purchase at the current price; (ii) "[a]s soon as the customers saw the price, they said that they have lived without it for five or six years and that they could live without it longer"; (iii) two Level I large bed trauma center hospitals in his/her district pushed back on the pricing of Andexxa and placed restrictions on who could use the drug; and (iv) Portola was "absolutely" struggling to sell Andexxa in the period leading up to its August 2019 Offering (*e.g.*, ¶¶148-51, 154, 157).

340. The truth that Andexxa was not "broadly" and "deeply" being utilized is further evidenced by the following statements by customers or potential customers who were marketed Andexxa by Portola:

- a. statements by CW7 that (i) s/he presented Andexxa to the P&T Committee, and it was felt that the data presented in the clinical trial was "flimsy;" (ii) nonetheless, the hospital felt that it was irresponsible to not carry the drug while prescribing Xarelto or Eliquis; it restricted use to only life-threatening intercranial bleeding for patients being treated with Xarelto or Eliquis, which s/he understands is consistent with how hospitals throughout the country are utilizing Andexxa; (iii) the hospital system

only stocks one high dose and one low dose of Andexxa because the usage is so limited, where the system only authorizes Andexxa's use for intercranial bleeding, which is normally accompanied by a stroke; (iv) in his/her hospital system, restrictions were based on effectiveness and not price; (v) the system only stocked one high and one low dose because the usage was so limited; (vi) the data on the use of Kcentra was as effective in many of the same situations as Andexxa; and (vii) it is his/her understanding that his/her hospital's practices are consistent with how hospitals throughout the country are utilizing Andexxa (*e.g.*, ¶¶162-64, 166-67);

- b. statements by CW8 that (i) his/her hospital system has Andexxa on its formulary but restricts its usage to only life-threatening events involving intercranial bleeding; (ii) the decision to restrict Andexxa's use is based on the cost versus benefit and the data presented in Portola's clinical trials; (iii) treatments such as Kcentra and Feiba have been used in the past and have been shown to be effective for less cost; (iv) throughout the entire hospital system, Andexxa has been used less than half a dozen times; (v) the data supporting use of Andexxa for GI bleeding was not enough to support its use for that type of bleed; (vi) Portola conducted an additional study of Andexxa, the results of which were presented at the American Society of Hospital Pharmacists convention in December 2019 in Las Vegas, Nevada and, in his/her opinion, the study was weak and still not convincing enough to change the Andexxa restrictions; and (vii) s/he

believes that most hospitals have similar restrictions on Andexxa (*e.g.*, ¶¶171, 173-75);

- c. statements by CW9 that (i) his/her team determined that the cost of Andexxa was too high when the benefits are compared with other medications, including PCC treatments such as Kcentra and Feiba, which were effective for significantly less cost; (ii) most hospitals in his/her hospital's peer group have made the same determination concerning Andexxa—that it is too costly when compared with other treatments; (iii) it is possible that, by carrying Andexxa, a hospital pharmacy may be unable to hire a technician or otherwise fill a vacant position; and (iv) Andexxa is a drug that would come out of the hospital pharmacy's budget (and third-party reimbursements do not affect the cost to the pharmacy department) (*e.g.*, ¶¶179, 181-83);
- d. statements by CW10 that (i) his/her hospital determined that the cost of Andexxa was too prohibitive to carry and that there was no justification for Andexxa's pricing when they could try other things; (ii) if they had a patient that was critical and needed Andexxa, then the patient should be immediately transferred by ambulance to a larger hospital within the area that carried Andexxa; and (iii) the hospital's CCO said that other drugs that were cheaper than Andexxa, such as Kcentra, could be used (*e.g.*, ¶¶188-189; and
- e. statements by CW13 that his/her hospital limits the use of Andexxa to intracranial bleeds due to cost (*e.g.*, ¶204).

341. The truth that Andexxa was not “broadly” and “deeply” being utilized is further evidenced by Garland’s statement attributing lack of utilization solely to available supply.

During the January 8, 2019 Conference Call, Garland commented that “I do know that when we spoke to customers about Q4 utilization, the #1 reason was actually *supply*. That was probably the main reason why accounts did not order.”

342. The truth that Andexxa was not “broadly” and “deeply” being utilized is further evidenced by the evasive responses by senior management to analyst questions during conference calls. For example, Garland downplayed whether 4F-PCCs and other pre-Andexxa treatments were being chosen over Andexxa on the Mar. 1, 2019 Conference Call, Garland said that the Company was seeing no issues concerning utilization on the Aug. 7, 2019 Conference Call (right before the August 2019 Offering), and Garland side-stepped a question regarding historical utilization at hospitals that had been stocking Andexxa for over the past year during the November 5, 2019 Conference Call:

- a. **[Analyst]:** ... where Andexxa is available, is it your understanding that that is clearly the first line therapy for the Xa bleeds or might there be some hospitals that while they have Andexxa available, are still using some of the older methods like fresh frozen plasma or four-factor PCCs even though that Andexxa is available?

[Garland]: Certainly, we know hospitals are using PCCs and we expect they probably will continue to use PCCs although we believe that’s inappropriate given the fact that we’re the only approved agent. But in many ways you call it, it really does vary by hospital. *It’s kind of hard to speak about it generally because each hospital is somewhat unique.* (¶227).

- b. **[Analyst]:** Does it concern among investors that over time as you get later doctors to stock a drug, their utilization is going to be less than the people who have stocked already. So the revenue curve is going to—going to begin to plateau or decelerate. What are your—what are your thoughts on that concern that’s in the market.

[Garland]: What we are seeing is we’ve looked at a cohort of our institutions, large important institutions that came on earlier at E[S]P and

actually what we’re seeing is increased usage over time or deepening usage over time. ***There’s nothing that we’re seeing today that makes us concerned about a lack of pull through or plateauing of our utilization.*** (¶257).

- c. [Analyst]: I’m just wondering if you could start to give ... some kind of on a comparison or, if it’s high level even about the current utilization at some of those hospitals that have been online for at least a year maybe even over a year versus maybe some that have come online in the past six month....

[Garland]: [N]ow that we’ve got a couple of years under—or a year under our belt how does the utilization look. We aren’t giving any detailed information around utilization per hospital per month. ***What we have seen is that, that utilization per hospital per month stays—has been staying consistent in 2019.*** (¶273).

343. Similarly, when asked by an analyst on the May 8, 2019 Conference Call to comment on timelines to go through “the hospital protocol review for Gen 2 relative to Gen 1,” Koenig started by acknowledging a 6 to 9 month process while also assuring that “we expect that rate to continue at a pretty linear rates to exactly what we’re saying and ***totally in line with our expectations.***” (¶242.) Garland on the same call also assured investors that the majority of the P&T efforts were in the past for the 300 hospital accounts acquired at that time: “***The majority of hospitals have made P&T decisions. And so the majority of them have the product on the protocol and are using the product....***” (¶243.)

344. The truth that Andexxa was not “broadly” and “deeply” being utilized is further evidenced by the actions of senior management during the Class Period to promote additional data to support the use of Andexxa over 4F-PCCs. Before and during the Class Period, CWs repeatedly communicated to senior management that Andexxa was having difficulty competing with 4F-PCCs because of cost and concerns regarding the efficacy of Andexxa (*see generally* ¶¶103(e), 103(f), 103(g), 108, 115, 124, 130, 137, 148, 153-56, 168, 175-76, 180, 194, 198, 206). The content of the following releases touting Andexxa over 4F-PCCs coupled with the timing of

these releases shows that Defendants knew that 4F-PCCs were a significant threat to Andexxa's launch but concealed such information from investors:

- a. On July 8, 2019, Portola announced new *in vitro* data establishing the relationship between concentrations of the direct oral anticoagulants apixaban and rivaroxaban and the ability of 4F-PCC to correct inhibition of thrombin generation, compared with warfarin anticoagulation reversal by 4F-PCC (§251); and
- b. On November 15, 2019, Portola issued a press release announcing that *Annals of Emergency Medicine*, the journal of ACEP, published a multidisciplinary anticoagulant reversal and replacement guidance statement. In the guidance statement, ACEP highlighted Andexxa as a first-in-line, FDA approved reversal agent for patients treated with apixaban or rivaroxaban, "as compared to 4F-PCC, which are highlighted as a second-in-line option for Factor Xa reversal and recommended for use only if Andexxa is not available." (§281).

345. The previously referenced actions by senior management during the Class Period of promoting additional data to support the use of Andexxa over 4F-PCCs demonstrates that Andexxa was not "broadly" and "deeply" being utilized in light of (i) the timing of the studies, (ii) comments by CWs, and (iii) an article published in *Seeking Alpha* on January 30, 2020 calling this additional Portola data into doubt:

- a. This data was pushed out only after Portola stopped relying on "reorder rate" (§268) and refused to answer specific questions about historical trends regarding demand and utilization during the November 5, 2019

analyst call (§273), and as the Company neared the end of the Class Period and the point when the truth about demand and revenue was going to emerge.

- b. CW8 stated that Portola conducted an additional study of Andexxa which was presented at the American Society of Hospital Pharmacist convention in December 2019 in Las Vegas, Nevada which, in his opinion, was weak and still not convincing enough to change the Andexxa restrictions. (§175.)

- c. On January 30, 2020, *Seeking Alpha* published a report authored by Edmund Ingham entitled: “Portola: Doubtful Trials And Falling Sales Make Andexxa An Unlikely Blockbuster.” Ingham discussed data Portola had published in 2019 claiming to support Andexxa as “best-in-class.” “Finally, Portola has published numerous pieces of research during 2019 supporting management’s claim that Andexxa is a best-in-class solution for treatment of Factor Xa related bleeds. ... As I will describe below however, *doubts have been cast about these results that are quite troubling and could prevent Andexxa from making it onto hospital formulary lists.*” (§297.)

346. The truth that Andexxa was not “broadly” and “deeply” being utilized is further evidenced by the following:

- a. the Company’s ultimate admissions on January 9, 2020 that the Portola encountered “[f]at quarter over quarter demand due to a decrease in utilization, primarily in tier 1 accounts” and that in certain of these

accounts, hospital pharmacies curtailed use of Andexxa following drug utilization reviews in an effort to manage pharmacy budgets” (§282);

- b. the Company’s admissions on January 14, 2020 that Andexxa sales had fallen because of “lower distributor purchases to manage inventory” in order “to keep their inventory levels at a constant level in the fourth quarter” (§§295-96);
- c. the Company’s acknowledgement on February 26, 2020 that the Company was “laser focused on driving near-term revenue growth [for Andexxa]” and was taking three important steps to “realign attention and resource allocation towards expanding the Andexxa customer base, driving utilization and increasing market share,” including the discontinuation of the limited remaining Bevyxxa operations (§301); and
- d. the Company’s admission in its FY 2019 Form 10-K filed on February 28, 2020 that it knew since Andexxa was approved by the FDA in early 2018 via the Accelerated Approval Program that the ANDEXXA-4 study proffered and relied up had “inherent limitations” that could impact the viability of Andexxa, where, for example, the Company was having significant difficulties competing with the off-label use of 4F-PCCs and other coagulation factors given a lack of comparative data and that hospital formulary committees were resistant to utilizing Andexxa because the Company lacked a clinical trial data comparing it to treatments used before Andexxa’s FDA approval (§§311-12).

347. These misstatements were material, non-puffery, because a reasonable investor would consider the fact that utilization for Andexxa was weaker than portrayed by the Company meant that Andexxa was not becoming the standard of care and that the Company's commercial launch was failing.

348. When considering the context in which these statements were offered, these misstatements were important to investors and analysts. Throughout the Class Period, Portola had disclosed as material in public filings the critical importance to the viability of Andexxa of creating and maintaining strong demand and utilization, as well as procuring a hospital's willingness to pay for Andexxa and to forgo use of cheaper, quasi-competitive 4PCC products, such as Kcentra. (¶¶96-99.) Portola made repeated statements that spoke to utilization throughout the Class Period, despite evidence to the contrary. (*Id.*; *e.g.*, ¶319.) Those statements were in that context materially misleading. Further, on the conference calls cited throughout, analysts repeatedly inquired directly into utilization and factors meant to serve as indicators of utilization, and misstatements made during those conference calls were materially false and misleading in that context as a result. (*E.g.*, ¶¶227, 242, 253, 257, 272-74, 285, 303, 324.)

349. These statements about utilization and its breadth and depth were fundamentally based on quantifiable metrics and information, which were capable of objective verification and consideration. Thus, statements about utilization were not statements of optimism, but rather statements premised on facts.

350. Further, analysts noted in reports throughout the Class Period that demand utilization of Andexxa were factors driving the commercial success of the Company:

- “[W]e continue to see notable upside in Portola shares as the commercial expansion of Andexxa into additional hospitals drives revenue growth and label expansions into emergency surgery and enoxaparin reversal increase the total market opportunity.” (William Blair, Apr. 4, 2019.)

- “The next few quarters will be critical to see how the initial demand translates into orders and sales and the likelihood of the product being able to achieve the \$1.34Bn in peak global sales that we currently forecast.” (Credit Suisse, May 8, 2019.)
- “[M]anagement remains very encouraged by the launch and believes it is progressing better than expected based on analogues of other hospital launches from the past 30 years. The message remains that the relatively slow uptake should not be unexpected at the outset of a hospital launch, the US demand for Andexxa is strong and growing.” (Credit Suisse, June 27, 2019.)
- “We are encouraged by the continued growth of Andexxa, particularly with 74% of sales in the quarter coming from hospitals reordering Andexxa. In addition, management commentary continues to be positive, highlighting the increased utilization trends with current accounts, recent increase in CMS NTAP reimbursement level (to 65% from 50%), access to the Veterans Administration health system, and first sales in Europe. We believe there is continued long[-]term momentum for Andexxa beyond the addition of new accounts over the next several quarters, including strong growth of the factor Xa class, label expansion to include urgent surgery and enoxaparin, and continued guidance recommendations including the recent Joint Commission updates.” (William Blair, Aug. 8, 2019.)
- “Andexxa is now available in roughly 550 hospitals in the United States, including another 125 new hospitals added in the quarter, and 76% of sales were from reorders as opposed to initial stocking (compared to 74% in the second quarter). We believe the continued uptake of Andexxa has been encouraging in both the United States and Europe, and continue to see a long-term opportunity for Andexxa through increasing penetration into a rapidly growing market.” (William Blair, Nov. 6, 2019.)

351. The significant stock drops on January 10, 2020, January 13, 2020, and February 27, 2020, which revealed the weak demand and utilization of Andexxa further demonstrate the materiality of these false and misleading statements. Further, analyst reports reacting to the news pointed specifically to issues of demand and utilization as factors both explaining the Company results and stock drops demonstrates the materiality of the false and misleading statements (*e.g.*, ¶¶287-93, 306-10).

**c. Defendants Made False and Misleading Statements
Concerning New Hospital Adds and Reorder Rate**

352. Throughout the Class Period, Defendants repeatedly touted two non-GAAP metrics: hospital adds and reorder rate. The Company portrayed these metrics as strong indicators that Andexxa was being well-received by hospitals, that Andexxa was receiving strong demand, and that the full commercial launch was a success. These statements were false. However, even if some are argued to be literally true – and they are not – the context and manner of their presentation make them false and misleading statements that do not have the ability to inform, but instead mislead, investors.

353. The following are a series of false and misleading statements concerning new hospital additions:

- “So you may remember on our Q3 call, we had mentioned that we’d stocked 100 hospitals. We now have stocked 200 hospitals. So *we’ve doubled the number of sites that we’ve begun stocking in the last quarter.*” (Garland, Jan. 8, 2019 Conference Call.)
- That “approximately 200 hospitals were stocking Andexxa by the end of the fourth quarter, with a reorder rate of approximately 50%. *That’s double the roughly 100 hospitals that were stocking Andexxa* at the end of the third quarter, with a reorder rate of approximately 40%. (Garland, Mar. 1, 2019 Conference Call.)
- “At the end of the first quarter we estimate that *approximately 300 hospitals were stocking Andexxa.*” (Koenig, May 8, 2019 Conference Call.)
- “Obviously the *125 [hospital] adds* that we have this quarter was ahead of expectations. I’ve been saying all along we expect a *linear uptake in hospital adds*, pretty much 100 a quarter.” (Garland, Aug. 7, 2019 Conference Call.)
- “In the [second quarter], *we added 125 additional hospitals* for a total of over 400 hospitals that have ordered Andexxa since launch.” (Prospectus.)
- “At the end of the third quarter *approximately 550 hospitals* in the U.S. had ordered Andexxa. This was our second consecutive quarter of

incremental hospital adds that exceeded our initial expectations.”
(Koenig, Nov. 5, 2019 Conference Call.)

354. The following are a series of false and misleading statements concerning “reorder rates”:

- “We’ve also seen *our reorder rate improve*. So the *percentage of accounts that have reordered was at 40% on our Q3 call, it’s now at 50% as of December 31*.... [W]e believe it’s truly *reflective of pull-through demand. Not just stocking, but real pull-through demand*.” (Garland, Jan. 8, 2019 Conference Call.)
- Koenig noted that the Company was “very happy with *what we’ve been seeing so far with the reorder rate*,” as those “reorder rates are really reflecting true *pull through and underlying demand*, we’ve seen this increase of 50% to 55%.” (Koenig, May 8, 2019 Conference Call.)
- “We also are beginning to see a consistent pattern *in the order and reorder rate*. At the end of the first quarter we estimate that approximately *300 hospitals were stocking Andexxa with our reorder rate of about 55%*. This increase is in line with our *overall trajectory thus far and we are seeing daily demand continue to grow*.” (Koenig, May 8, 2019 Conference Call.)
- Garland said that “as we’ve said before, *the that reorder is obviously influenced by the denominator*. If you look back at hospitals that came on earlier in the launch of Andexxa that reorder rate is significantly higher than the percentage for all hospitals so far. So as Sheldon mentioned, we’re very happy with where the reorder rate and is—and as hospitals maturities to that *reorder rate continue to increase*.” (Garland, May 8, 2019 Conference Call.)
- “We track the number of accounts that have ordered at least once. You might call that sort of new store growth. So what we’ve seen quarter-on-quarter is about 100 new hospitals ordering each quarter. So as of the end of the first quarter, we have 300 accounts that had ordered at least once. That was up from 200 the prior quarter, so Q4 of the prior year. *In addition, we look at pull-through, right?* So there is both the *new store growth but also the same-store growth, so accounts that continue to reorder*. And so the metric we track there is *reorders*. The *reorder rate for the first quarter of 2019 was at 55%. That was up from 50% the prior quarter*.” (Garland, June 11, 2019 Goldman Sachs Global Healthcare Conference Call.)
- That “*74% of our sales in the quarter came from reorders, reflecting real pull through and increasing use in patients*. In addition, *our reorder*

rate remained steady at 55% for the quarter, in tandem with an incremental number of hospital adds that was beyond our expectations, and a significant percent of new hospitals coming on late in the quarter.” (Garland, Aug. 7, 2019 Conference Call.)

- “As Scott mentioned, *our reorder rate in the second quarter was approximately 55%*. More importantly, *reorders in the second quarter grew to 74% of our total Andexxa revenues reflecting real pull through and increasing use in patients.*” (Koenig, Aug. 7, 2019 Conference Call.)
- That “in the second quarter of 2019, *Andexxa had a reorder rate of 54% with 74% of Andexxa revenues from reorders for the quarter.*” (Prospectus.)
- That “existing accounts continued to show *strong pull-through*, with *76% of sales in the quarter coming from utilization or reorders compared to 74% in the previous quarter. This is an important metric because it reflects demand and significant pull-through in hospitals* where Andexxa is being used to treat patients. Also inventory in the channel remained steady at approximately two weeks of demand.” (Koenig, Nov. 5, 2019 Conference Call.)
- “We think *the number [% of sales driven by reorders]* is great. *It’s a real sign of great pull-through with the product.*” (Garland, Nov. 5, 2019 Conference Call.)
- “The *reorder rate also remained steady at 56%* for the quarter. While this is encouraging, we believe this metric is impacted by the variability in the timing, mix and number of our new hospital additions each quarter.” (Koenig, Nov. 5, 2019 Conference Call.)

355. The bolded and italicized statements in ¶¶353-54, that the new hospitals additions and reorder rates showed growth and demand for Andexxa were affirmative statements of present fact that were materially false and misleading when made because (i) the new hospital additions included hospitals that did not intend to use Andexxa, but stock it only for liability purposes only, or so heavily restricted Andexxa use that it was unlikely that the Andexxa stock would ever be used, and (ii) the “reorder rate” was not a valid indicator of demand and pull-through in hospitals particularly because it concealed the magnitude of reorders and included all hospitals in its calculation whether they had been stocking Andexxa for several

quarters or were added just recently. It is further materially false and misleading because what contributes to “reorder rates” is neither defined nor known. For example, does “reorder rate” include exchanges of returned expired or short-shelf-life doses for longer-life doses? Does it include the return of original 100 mg FDA-approved Andexxa for newly-FDA-approved 200 mg Andexxa? These inputs, if included, would be extraordinarily misleading.

356. The truth that “new hospitals added” and “reorder rates” were not reliable metrics to show demand for Andexxa is evidenced by the following statements by former employees of Portola:

- a. statements by CW1 that (i) hospitals had difficulty justifying the high cost of Andexxa and that they could rely on other treatments that they had been using for years without spending as much; (ii) the data concerning the effectiveness of Andexxa did not justify the cost versus the benefit; (iii) some hospitals were carrying Andexxa as a “CYA” and did not intend to use it; and (iv) because of price, a hospital covered by CW1 had very restrictive use protocols in place limiting Andexxa’s use to life-threatening intracranial bleeds (*e.g.*, ¶¶106-07);
- b. statements by CW3 that (i) sales of Andexxa were stagnant throughout his/her time at Portola selling the drug; (ii) Andexxa’s price was problematic, “[i]t was a struggle for [him/her] from day one to sell Andexxa,” and “the hospital pharmacists were terrified of [Andexxa] and not from a clinical point[, but] strictly from a cost point”; (iii) small, rural hospitals that CW3 called on believed that Andexxa was priced “way too aggressively” and many could not afford it; (iv) a hospital with 100 beds

or less would have to make a choice between purchasing Andexxa and hiring a staff member because of the high cost; (v) Kcentra, another anticoagulant reversal drug, was a cheaper alternative to Andexxa for many hospitals; and (vi) a professor of pharmacology and clinical specialist paid to speak on the benefits of Andexxa by Portola at a June 2018 Hospital Pharmacy Society conference that was attended by 55 hospital pharmacists stated that he would nonetheless use Kcentra over Andexxa because of its cost (*e.g.*, ¶¶118-20, 122-23);

- c. statements by CW4 that (i) sales of Andexxa were slow throughout the time that s/he worked at Portola and sold Andexxa; (ii) hospital pharmacists were shocked at the price difference between Kcentra and Andexxa, and that cost was the reason for slow sales; (iii) s/he believed that hospitals were initially worried about being sued if a patient died following a severe bleed and the particular hospital did not carry Andexxa, but an article written by three pharmacists in 2019 provided hospital pharmacy directors with information to push back on ordering Andexxa; (iv) many hospitals used the publication of the article to further bolster their position that Andexxa was too expensive to carry when a cheaper alternative such as Kcentra was available; and (v) the high cost of Andexxa put a strain on pharmacy budgets (*e.g.*, ¶¶126, 127, 129, 131);
- d. statements by CW5 that (i) from his/her perspective, the biggest issues Portola had concerning Andexxa usage was the cost of the drug combined with the off-label use of Kcentra; (ii) Andexxa was very expensive and

sales stayed at a consistent level until there was a decline; (iii) through his/her own observations and communications with other sales reps, the rate of sales of Andexxa were not increasing during 2019 throughout the Class Period; (iv) pharmacies made the purchasing decisions, and they told doctors who wanted Andexxa that the drug was not available or that its use was restricted and that Kcentra was the only available treatment on the formulary; (v) while sales numbers were steady, some hospitals stocked up but did little reordering; (vi) s/he heard from other sales reps that beginning in the second half of 2019, there was an increase in the volume of returns, which s/he described as a large amount of returns of Andexxa; (vii) he/she believes that hospitals made a cost versus utilization analysis and determined that it was too costly to stock more than 3 to 5 boxes of Andexxa or to reorder additional boxes given that the indications were so limited; and (viii) insurance coverage does not affect a hospital pharmacy department's decision about whether to purchase Andexxa because third-party reimbursement tends to go back to the general hospital accounts and generally does not get refunded to the pharmacy department's budget (*e.g.*, ¶¶137-39, 142-43, 146);

- e. statements by CW6 that (i) many hospitals refused to add Andexxa to their formularies because of its high price, telling him/her that they have learned to manage bleeding with these patients and that they have strategies that have been working so they wouldn't purchase at the current price; (ii) "[a]s soon as the customers saw the price, they said that they

have lived without it for five or six years and that they could live without it longer”; (iii) two Level I large bed trauma center hospitals in his/her district pushed back on the pricing of Andexxa and placed restrictions on who could use the drug; (iv) 90% of his/her customer calls responded with a “flat-out ‘no;’” and (v) Portola was “absolutely” struggling to sell Andexxa in the period leading up to its August 2019 Offering (*e.g.*, ¶¶148-51, 154, 157); and

- f. statements by CW12 that (i) working in the San Francisco headquarters, s/he was aware that the sales of Andexxa were not going well via “lunchroom” conversation with people in the Sales Division; and (ii) s/he believes that, in the Spring of 2019, sales had “come down,” based on lunchroom conversations with sales staff, who were asking why sales were not going well (*e.g.*, ¶¶197, 199).

357. The truth that “new hospitals added” and “reorder rates” were not reliable metrics to show demand for Andexxa is further evidenced by the following statements by customers or potential customers who were marketed Andexxa by Portola:

- a. statements by CW7 that (i) s/he presented Andexxa to the P&T Committee, and it was felt that the data presented in the clinical trial was “flimsy;” (ii) nonetheless, the hospital felt that it was irresponsible to not carry the drug while prescribing Xarelto or Eliquis; it restricted use to only life-threatening intercranial bleeding for patients being treated with Xarelto or Eliquis, which s/he understands is consistent with how hospitals throughout the country are utilizing Andexxa; (iii) the hospital system

only stocks one high dose and one low dose of Andexxa because the usage is so limited, where the system only authorizes Andexxa's use for intercranial bleeding, which is normally accompanied by a stroke; (iv) in his/her hospital system, restrictions were based on effectiveness and not price; (v) it is not that Andexxa is ineffective, but it is only appropriate for certain indications and is not a "miracle drug;" (vi) the data on the use of Kcentra was as effective in many of the same situations as Andexxa; and (vii) it is his/her understanding that his/her hospital's practices are consistent with how hospitals throughout the country are utilizing Andexxa (*e.g.*, ¶¶162-64, 166-67);

- b. statements by CW8 that (i) his/her hospital system has Andexxa on its formulary but restricts its usage to only life-threatening events involving intercranial bleeding; (ii) the decision to restrict Andexxa's use is based on the cost versus benefit and the data presented in Portola's clinical trials; (iii) treatments such as Kcentra and Feiba have been used in the past and have been shown to be effective for less cost; (iv) throughout the entire hospital system, Andexxa has been used less than half a dozen times; (v) the data supporting use of Andexxa for GI bleeding was not enough to support its use for that type of bleed; (vi) Portola conducted an additional study of Andexxa, the results of which were presented at the American Society of Hospital Pharmacists convention in December 2019 in Las Vegas, Nevada and, in his/her opinion, the study was weak and still not convincing enough to change the Andexxa restrictions; and (vii) s/he

believes that most hospitals have similar restrictions on Andexxa (*e.g.*, ¶¶171, 173-75);

- c. statements by CW9 that (i) his/her team determined that the cost of Andexxa was too high when the benefits are compared with other medications, including PCC treatments such as Kcentra and Feiba, which were effective for significantly less cost; (ii) most hospitals in his/her hospital's peer group have made the same determination concerning Andexxa—that it is too costly when compared with other treatments; (iii) it is possible that, by carrying Andexxa, a hospital pharmacy may be unable to hire a technician or otherwise fill a vacant position; and (iv) Andexxa is a drug that would come out of the hospital pharmacy's budget (and third-party reimbursements do not affect the cost to the pharmacy department) (*e.g.*, ¶¶179, 181-83);
- d. statements by CW10 that (i) his/her hospital determined that the cost of Andexxa was too prohibitive to carry and that there was no justification for Andexxa's pricing when they could try other things; (ii) if they had a patient that was critical and needed Andexxa, then the patient should be immediately transferred by ambulance to a larger hospital within the area that carried Andexxa; and (iii) the hospital's CCO said that other drugs that were cheaper than Andexxa, such as Kcentra, could be used (*e.g.*, ¶¶188-89); and
- g. statements by CW11 that (i) high cost is why Andexxa was kept off the hospital's formulary, where the hospital had a cheaper, reasonable

alternative in Feiba; (ii) both a 2018 P&T Committee review of Andexxa as well as a review by medical staff informed and supported that position; and (iii) s/he believes that many other hospitals in his/her state made a similar choice as his/her facility to not add Andexxa to their formularies (e.g., ¶¶191-93); and

- e. statements by CW13 that (i) his/her hospital limits the use of Andexxa to intercranial bleeds due to cost; (ii) his/her hospital carries it for fear of liability; and (iii) that s/he believes other hospitals in his/her region that accept critical patients from his/her hospital do not carry Andexxa due to cost (e.g., ¶¶203-05).

358. The truth that “new hospitals added” and “reorder rates” were not reliable metrics to show demand for Andexxa is further evidenced by an admission made by Garland during the Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call when he stated that the Company could not rely on it and shifted to a new metric percentage of revenue from reorders, and by a response that Garland gave to a question during the November 5, 2019 Q3 2019 analyst call when he was asked where he had seen the reorder rate trending and what the Company expected for the rate going forward and he avoided substantively answering the past trend question and declined to provide “*any sort of* forward-looking guidance:”

- a. **[Garland:]** The reorder rate, we’ve talked about before, it was 55%, which was stable quarter-on-quarter, is heavily influenced by when a hospital comes online. And remember, we added 125 hospitals in the second quarter. Many of those were later in the quarter. And as a result, they are in the denominator, but they haven’t been around long enough to contribute to the numerator. *So that had an impact on the reorder rate, which is why we gave it a new metric, which was that roughly 3/4 of our business, or 74% of our business, came from reorders.* So what we’re seeing consistently is that the drug is getting utilized. (¶268.)

- b. **[Analyst]:** [O]n the 76% of sales, *revenue driven by reorders, can you just comment on where you see that number trending? And it seems like it's leveling off a bit.* Is that how – what you expect at this point in the launch?

[Garland]: *[W]e haven't and won't be providing any sort of forward-looking guidance on the reorder rate.* It obviously went up quarter-over-quarter. I do expect, though, that, that number is not going to be 100%. (¶273.)

359. The truth that these metrics did not fairly evidence demand is shown by the actions of senior management during the Class Period of promoting additional data to support the use of Andexxa over 4F-PCCs. Before and during the Class Period, CWs repeatedly communicated to senior management that Andexxa was having difficulty competing with 4F-PCCs because of cost and concerns regarding the efficacy of Andexxa (¶¶90, 127-129). The content of the following releases touting Andexxa over 4F-PCCs coupled with the timing of these releases shows that Defendants knew that 4F-PCCs were a significant threat to Andexxa's launch but concealed such information from investors:

- a. On July 8, 2019, Portola announced new *in vitro* data establishing the relationship between concentrations of the direct oral anticoagulants apixaban and rivaroxaban and the ability of 4F-PCC to correct inhibition of thrombin generation, compared with warfarin anticoagulation reversal by 4F-PCC. (¶251.)
- b. On November 15, 2019, Portola issued a press release announcing that Annals of Emergency Medicine, the journal of ACEP, published a multidisciplinary anticoagulant reversal and replacement guidance statement. In the guidance statement, ACEP highlighted Andexxa as a first-in-line, FDA approved reversal agent for patients treated with

apixaban or rivaroxaban, “as compared to 4F-PCC, which are highlighted as a second-in-line option for Factor Xa reversal and recommended for use only if Andexxa is not available.” (§281.)

360. The previously referenced actions by senior management during the Class Period of promoting additional data to support the use of Andexxa over 4F-PCCs demonstrates that these metrics did not fairly evidence demand when viewed in light of (i) the timing of the studies, (ii) comments by a CW, and (iii) an article published in *Seeking Alpha* on January 30, 2020 calling this additional Portola data into doubt:

- a. This data was pushed out only after Portola stopped relying on “reorder rate” (§268) and refused to answer specific questions about historical trends regarding demand and utilization during the November 5, 2019 analyst call (§273), and as the Company neared the end of the Class Period and the point when the truth about demand and revenue was going to emerge;
- b. CW8 stated that Portola conducted an additional study of Andexxa which was presented at the American Society of Hospital Pharmacist convention in December 2019 in Las Vegas, Nevada which, in his/her opinion, was weak and still not convincing enough to change the Andexxa restrictions (§175); and
- c. On January 30, 2020, *Seeking Alpha* published a report authored by Edmund Ingham entitled “Portola: Doubtful Trials And Falling Sales Make Andexxa An Unlikely Blockbuster.” Ingham discussed data Portola had published in 2019 claiming to support Andexxa as “best-in-class.”

“Finally, Portola has published numerous pieces of research during 2019 supporting management’s claim that Andexxa is a best-in-class solution for treatment of Factor Xa related bleeds. ... As I will describe below however, *doubts have been cast about these results that are quite troubling and could prevent Andexxa from making it onto hospital formulary lists*” (¶297).

361. The truth that “new hospitals added” and “reorder rates” were not reliable metrics is further evidenced by the following:

- a. the Company’s ultimate admissions on January 9, 2020 that the Portola encountered “[f]at quarter over quarter demand due to a decrease in utilization, primarily in tier 1 accounts” and that in certain of these accounts, hospital pharmacies curtailed use of Andexxa following drug utilization reviews in an effort to manage pharmacy budgets” (¶282);
- b. the Company’s admissions on January 14, 2020 that Andexxa sales had fallen because of “lower distributor purchases to manage inventory” in order “to keep their inventory levels at a constant level in the fourth quarter” (¶¶295-96);
- c. the Company’s acknowledgement on February 26, 2020 that the Company was “laser focused on driving near-term revenue growth [for Andexxa]” and was taking three important steps to “realign attention and resource allocation towards expanding the Andexxa customer base, driving utilization and increasing market share,” including the discontinuation of the limited remaining Bevyxxa operations (¶301); and

- d. the Company's admission in its FY 2019 Form 10-K filed on February 28, 2020 that it knew since Andexxa was approved by the FDA in early 2018 via the Accelerated Approval Program that the ANDEXXA-4 study proffered and relied up had "inherent limitations" that could impact the viability of Andexxa, where, for example, the Company was having significant difficulties competing with the off-label use of 4F-PCCs and other coagulation factors given a lack of comparative data and that hospital formulary committees were resistant to utilizing Andexxa because the Company lacked a clinical trial data comparing it to treatments used before Andexxa's FDA approval (§§311-12).

362. These misstatements were material because a reasonable investor would have relied on these metrics because Portola viewed these as reliable indicators of demand for Andexxa and showed that the commercialization of Andexxa was a success. Further, analysts noted in reports throughout the Class Period that demand utilization of Andexxa were factors driving the commercial success of the Company:

- "[W]e continue to see notable upside in Portola shares as the commercial expansion of Andexxa into additional hospitals drives revenue growth and label expansions into emergency surgery and enoxaparin reversal increase the total market opportunity." (William Blair, Apr. 4, 2019.)
- "The next few quarters will be critical to see how the initial demand translates into orders and sales and the likelihood of the product being able to achieve the \$1.34Bn in peak global sales that we currently forecast." (Credit Suisse, May 8, 2019.)
- "[M]anagement remains very encouraged by the launch and believes it is progressing better than expected based on analogues of other hospital launches from the past 30 years. The message remains that the relatively slow uptake should not be unexpected at the outset of a hospital launch, the US demand for Andexxa is strong and growing." (Credit Suisse, June 27, 2019.)

- “We are encouraged by the continued growth of Andexxa, particularly with 74% of sales in the quarter coming from hospitals reordering Andexxa. In addition, management commentary continues to be positive, highlighting the increased utilization trends with current accounts, recent increase in CMS NTAP reimbursement level (to 65% from 50%), access to the Veterans Administration health system, and first sales in Europe. We believe there is continued long[-]term momentum for Andexxa beyond the addition of new accounts over the next several quarters, including strong growth of the factor Xa class, label expansion to include urgent surgery and enoxaparin, and continued guidance recommendations including the recent Joint Commission updates.” (William Blair, Aug. 8, 2019.)
- “Andexxa is now available in roughly 550 hospitals in the United States, including another 125 new hospitals added in the quarter, and 76% of sales were from reorders as opposed to initial stocking (compared to 74% in the second quarter). We believe the continued uptake of Andexxa has been encouraging in both the United States and Europe, and continue to see a long-term opportunity for Andexxa through increasing penetration into a rapidly growing market.” (William Blair, Nov. 6, 2019.)

363. The significant stock drops on January 10, 2020, January 13, 2020, and February 27, 2020, which revealed the weak demand and utilization of Andexxa further demonstrate the materiality of these false and misleading statements. Further, analyst reports reacting to the news pointed specifically to issues of demand and utilization as factors both explaining the Company results and stock drops demonstrates the materiality of the false and misleading statements (*e.g.*, ¶¶287-93, 306-10).

2. Defendants Issued False and Misleading Statements Regarding Its Financial Reporting and Results

364. During the Class Period, Defendants issued several categories of materially false and misleading statements regarding its financial results, namely (i) materially false and misleading misrepresentations regarding the Company’s compliance with GAAP; (ii) materially false and misleading net revenue figures; (iii) materially false and misleading statements regarding the Company’s compliance with its own internal Revenue Recognition Policy; and (iv) materially false and misleading SOX Certifications.

a. Defendants Issued Materially False And Misleading Statements Regarding Portola's Compliance With GAAP

365. As discussed above, the Company represented in each of its financial reports issued during the Class Period that it prepared its financials in compliance with GAAP and ASC 606, including its (i) FY 2018 Form 10-K; (ii) Q1 2019 Form 10-Q; (iii) Q2 2019 Form 10-Q; and (iv) Q3 2019 Form 10-Q (collectively, the “Financial Reports”).

366. In its Financial Reports, the Company represented that its revenue figures were net of reserves for variable consideration, including returns, discounts, chargebacks, and other variables. The FY 2018 Form 10-K and FY 2019 Form 10-K results demonstrate that a significant majority of Portola's reported reserves were for returns. Attached hereto as **Exhibit 3** is a chart prepared from information and figures contained in the Financial Reports issued during the Class Period as well as the FY 2019 Form 10-K, which summarizes reserve figures taken for each of these reporting periods.

367. The representations in each of the Financial Reports that the Company complied with GAAP and ASC 606 were materially false and misleading because the Company lacked a reasonable basis, including sufficient relevant historical evidence and other factual bases, to recognize revenue under ASC 606. More specifically, Defendants ***lacked sufficient relevant historical evidence and other facts to conclude “that it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur,”*** which was required for the Company to report revenues. As such, Portola was precluded from recognizing revenue upon sell-in, *i.e.*, upon shipment to its distributors.

(1) Portola's Burden Under ASC 606

368. As detailed in Section V.F. above, ASC 606 sets forth the core principle that an entity can only recognize revenue in an amount that reflects the consideration to which the entity

expects to be entitled in exchange for the goods sold. *See* ASC 606-10-05-3. If the consideration is variable, such as where there exists rights of return, an entity must estimate the amount of consideration to which it is entitled according to a five-step process to assess how much, if any, revenue to recognize. ASC 606-10-05-4. Under Step No. 3, Portola was required to determine “[t]ransaction price” prior to recognizing revenue for its product sales.

369. ASC 606-10-32-1 through ASC 606-10-32-14 impose requirements on a company for how to determine the *transaction price* when rights of return exist. An expected value may be an appropriate estimate of the amount of variable consideration if an entity has a large number of contracts with similar characteristics. ASC 606-10-32-8 defines the expected value as being the sum of probability-weighted amounts in a range of possible consideration amounts.

370. However, the estimated amount of variable consideration may be included in the transaction price “*only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.*” ASC 606-10-32-11. That is, to the extent Portola was unable to conclude that *it was probable that a significant reversal in the amount of cumulative revenue recognized would not occur, it was precluded from recognizing revenue* (*i.e.*, the revenue recognition constraint). In assessing whether it is probable that a significant reversal in the amount of cumulative revenue will not occur, an entity shall consider both *the likelihood* and *the magnitude* of the potential revenue reversal.

371. For example, ASC 606-10-32-12 requires that companies consider factors that could increase the likelihood or the magnitude of a revenue reversal, including the following, which are highly relevant here: (a) that the amount of consideration is highly susceptible to factors outside the entity’s influence, such as a high risk of obsolescence of the promised good or

service; (b) that the uncertainty about the amount of consideration is not expected to be resolved for a long period of time; (c) that the entity's experience with similar types of contracts is limited, or that experience has limited predictive value; and (d) that the contract has a large number and broad range of possible consideration amounts.

372. As discussed below, because the Company offered its Customers (distributors) and end users (hospitals) a ***broad right of return*** and ***lacked sufficient relevant historical evidence and the existence other factual conditions during the Class Period***, Portola should not have recognized revenue at the time of sale to the distributors because it could not reasonably conclude, based on the relevant facts surrounding its sales, that it was probable that a significant reversal in the amount of revenue would not occur in accordance with ASC 606-10-32-11 through ASC 606-10-32-13. *See* ASC 606-10-55-227 through ASC 606-10-55-232.

373. Indeed, an evaluation of the factors discussed above reflects the absence of sufficient relevant historical evidence and other factual data necessary to overcome the revenue recognition constraint in ASC 606 and conclude that it was probable that a significant reversal in the amount of Portola's cumulative revenue recognized would not occur when the uncertainty associated with the variable consideration (*i.e.*, the return of product) was subsequently resolved. Specifically, (a) Portola's asserted sales of short-dated Andexxa (*i.e.*, 6-12 month expiration dates) exposed the Company to a higher risk of obsolescence increasing the likelihood of the products' return and a revenue reversal; (b) Portola's ability to estimate product returns with relevant historical experience with similar contracts was inherently limited given the initial, limited non-commercialized release of Andexxa in May 2018 and the absence of relevant sales and return-related experience; (c) uncertainties about the amount of consideration Portola would ultimately receive was not expected to be resolved for a long time (***up to 18 months after sale***);

and (d) the possible significant variation in transaction price as a result of other factors outside of Portola's control including, but not limited to, market use and acceptance given the alternative, less costly treatment alternatives available. Each of these factors are discussed in greater detail below and precluded Portola from recognizing upfront revenue.

(2) Portola lacked sufficient relevant historical evidence and other facts to determine “that it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur”

374. The fact that Portola lacked a reasonable basis, including relevant historical evidence and other factual bases, to conclude that “it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur” is *first* evidenced by the fact that the Company did not have *any* sufficient relevant historical sales and return data with which to conclude that it was “probable” that there would not be a significant reversal in the amount of reversal due to returns. While relevant historical evidence could be either company-specific (same product, similar product, etc.) or market specific historical experience, the Company admittedly lacked both:

- a. From the Company's perspective, it lacked any reliable historical sales data for either Andexxa or any other product. Indeed, as it admitted in its FY 2018 Form 10-K issued at the beginning of the Class Period, “We are an early stage commercial biopharmaceutical company. We launched our first commercial products in 2018.” Andexxa only received FDA approval for limited Early Supply Program sales in May 2018 and for commercial sale on December 31, 2018. As stated in its FY 2018 Form 10-K, the Company's had no meaningful sales history for its products: “product revenue consists of the U.S. sales of Andexxa, which we began

shipping to customers in May 2018, and the U.S. sales of Bevyxxa, which we began shipping to customers in January 2018. Prior to January 2018 we had no product revenues.”⁶⁵ Indeed, as of December 31, 2018, the Company only had global product net revenue of \$24.1 million and net product revenue of \$24 million for sales of Andexxa and as of December 31, 2019, its global net product revenue was only \$111.6 million and its net product revenue of Andexxa was only \$104.5 million.⁶⁶ In its FY 2018 Form 10-K, the Company further conceded that “We are still in the early stages of developing our sales and marketing infrastructure.” In that FY 2019 Form 10-K, Defendants further admitted that ***“[a]uditing the Company’s measurement of reserves for product returns under its contracts with customers was especially challenging because (1) the calculation involves subjective management assumptions about inventory remaining in the distribution channel as of the balance sheet date (i.e., units held by hospitals) that could be subject to return in future periods under the Company’s returns policy, and (2) the Company has limited commercial sales history on which to base its assumptions.”***

⁶⁵ Indeed, in its 2019 FY Form 10-K, the Company admitted that “To date, we have financed our operations primarily through sales of our equity securities, collaborations, including a loan from one of our collaboration partners, a sale of a royalty stream from future product sales, a term loan, sales of commercial and development rights to some of our product candidates, and to a lesser extent, government grants, equipment leases, venture debt and with the benefit of tax credits made available under a federal stimulus program supporting drug development.” This statement was repeated throughout the Class Period, with only minor word changes.

⁶⁶ Losses totaled \$350.5 million and \$292.9 million in FY 2018 and FY 2019, respectively.

- b. The Company also lacked any data from market-specific historical data because there were no comparable products on the market from a sales perspective. As the Company noted in its FY 2018 Form 10-K, “there are no therapies other than Andexxa approved specifically as antidotes for Factor Xa inhibitors.” The Company repeatedly touted the fact that there was no other antidote for patients treated with rivaroxaban or apixaban during the Class Period, including in each Form 10-Q issued during the Class Period and in its FY 2019 Form 10-K. At a November 14, 2019 Investor Day conference, Dr. Alvin Schmaier, an oncologist speaking on behalf of Portola, said that Andexxa “is focused towards an unmet need and that is correction of bleeding of individuals who are on these oral anti-Xa. There is no comparative.” In Portola’s January 14, 2020 Corporate Update Call, Garland touted that “Andexxa is a unique drug, it’s a highly innovative novel therapy, it was granted breakthrough designation and orphan drug status by the FDA.” He further noted that “Andexxa is a highly differentiated drug.” During the Feb. 26, 2020 Conference Call, Garland further touted that “*Andexxa is a novel product, addressing an unmet need in a large and growing market.*” While there were other drugs that have been used off-label as such a therapy, none of these were sold at the exorbitant prices at which Portola sold Andexxa, a fact that goes to the core of its commercial marketability and, thus, the viability of its revenues.

375. In sum, as the Company conceded in its FY 2018 Form 10-K and repeated nearly verbatim throughout the Class Period that the absence of historical sales data made it difficult to predict product sales:

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. ***Due to the recent approval by the FDA of our products and the absence of historical sales data, our product sales will be difficult to predict from period to period.***

376. The fact that the Company lacked a reasonable basis, including relevant historical evidence and other factual bases, to conclude that “it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur” is ***further*** evidenced by the ***confluence*** of the following facts, ***all of which existed contemporaneously with the Company’s decision to recognize the revenue:***

- a. Revenue was recognized when product was sold to distributors, not when it was later ordered by and sold to hospitals. (¶¶218, 229-30.)
- b. As described in ¶100 above, the Company’s generous formal written return policy allowed returns from either the distributors ***or*** the hospitals:
 - i. within 3 months of the product’s expiration date or 6 months after its expiration date
 - ii. if the product was unused and unopened (¶100.)
- b. CWs 1, 4, 5, 6, and 8 confirmed that Portola had liberal return policy and collectively confirmed that Portola allowed customers to return shorter-dated product for a longer-dated product, return lower-dose product for a higher-dose product, and return a product that was intended for a patient who died before it could be administered. (*E.g.*, ¶¶112, 133, 144, 159, 177.)

- c. As discussed above, the Company initially sold short-dated product that had a 6- to 12-month expiration date knowing that it would release a longer-dated product, thereby increasing the risk of return. As Koenig admitted in the Jan. 9, 2020 Conference call, “the decision was made to go out with that dating ... to get the medicine to patients as quickly as possible.” (E.g., ¶286.) Then it was permitted to sell longer dated product with a 24-month expiration. (e.g., ¶88.) Then, in November 2019, the Company started selling Andexxa with a 36-month expiration date. (E.g., ¶¶284-85.) Given that hospitals were entitled to return short-dated product for longer dated product that was available or about to become available, the risk of returns should have been a serious concern throughout 2019, increased the likelihood of return of short-dated product, and created further uncertainty as to whether a significant reversal of consideration would be required for short-dated Andexxa contracts.
- d. Portola did not track what the expiration date was when product was sold to hospitals from the distributors. Indeed, as Garland noted at the Jan. 9, 2020 Conference Call, “I should emphasize that the dating of 6 to 12 months is when it got to the distributor. *What the actual dating was when it was shipped to the end customer, we don’t have that visibility*, but that’s essentially what it was when we shipped to our distributors.” (E.g., ¶286.) *Accordingly, the Company had no ability or effective process in place to assess what product was likely or not likely to be returned by the ultimate users, the hospitals, during the Class Period.* This lack of

visibility into the channel created further uncertainties regarding the risk and magnitude of product returns.

- e. As the hospital and salesperson CWs reported, (i) the high price of Andexxa was hindering sales; (ii) demand for Andexxa was not strong since many hospitals refused to order Andexxa, choosing instead to purchase Kcentra and other alternatives due to cost concerns; and (ii) hospitals that were ordering Andexxa were restricting its usage both because of cost concerns and the lack of clinical data to support broader utilization. (¶¶118, 120, 122, 126, 131, 138, 139, 163, 171, 174, 175, 179, 181, 188, 191, 192, 193, 204.) The uncertainties surrounding market acceptance, due in part to the high cost of the drug and a viable alternative, further affected Portola's ability to conclude that a significant reversal of revenue was not probable.
- f. Moreover, as set forth above, Defendants knew or were deliberately reckless in not knowing about these issues. (*See, e.g.*, Section VI.B. ("Additional Allegations of Scierter").)
- g. the Company needed to reach a revenue milestone of \$50 million in reported net sales in compliance with GAAP for Andexxa by the end of the third quarter of 2019 to access the second \$62.5 million tranche of its Secured Term Loan. (¶68.)

377. Each of these concerns are the very factors that ASC 606-10-32-12 requires be given due consideration. These facts, combined with the lack of relevant historical evidence for Andexxa or a comparable drug, demonstrate that there was no basis upon which the Company

could determine “*that it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur.*” Therefore, in reporting any or all of the revenue reported upon sell-in to its distributors, Portola violated GAAP by ignoring that there existed serious concerns regarding the length of uncertainty of whether and when Andexxa sales might be returned due to expiring dates, price concerns, restrictions on use, and lack of utilization. ASC 606-10-32-11 through ASC 606-10-32-13. Until the right of return has lapsed or it was reasonably concluded that it was probable, that is, likely that a significant portion of the amount recognized would not be reversed, the Company should not have recognized the revenue it reported in its Financial Reports. Since product sales for Andexxa did not begin until May 2018, sales of Andexxa short-dated product (*i.e.*, expiration periods of between 6 to 12 months) during 2018 and most of 2019 would not in most cases have reached its expiration in time to generate sufficient historical data to calculate any remotely reliable rate and amount of forecasted product returns for either 2018 or 2019. Compounding this difficulty in estimating revenue was the existence of Kcentra, a competing and far less expensive substitute product. As certain of the CWs have explained above, the existence of more cost effective alternatives, such as Kcentra, created serious sales and product use obstacles, which were well known by Defendants during the Class Period.

378. The fact that the Company lacked a reasonable basis, including relevant historical evidence and other factual bases, to conclude that “it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur” is *further* evidenced by the confluence of the following admissions by the Company at the end of the Class Period:

- a. The Company’s January 9, 2020 and February 26, 2020 admissions that there was a decrease in utilization, primarily in Tier 1 accounts (consistent

with the CW reports) and that they lacked visibility into utilization trends.
(*E.g.*, ¶¶282, 289, 292, 299-300, 303.)

- b. The Company's *new* risk disclosure conceding, *for the first time* in the FY 2019 Form 10-K, that the fact that Andexxa *lacked clinical data* comparing its efficacy with that of "widely used" 4F-PCCs like Kcentra had affected its ability to compete with a common standard of care preceding Andexxa and conceding that Portola knew that Kcentra and other 4F-PCCs *were still being used over Andexxa* (consistent with the CW reports):

[W]e do not have comparator arm data, including clinical head to head data against the treatment options which were used by hospitals prior to the availability of Andexxa, **which we believe continue to be widely used**, including off-label use of 4F-PCCs and other coagulation factors. In addition, the efficacy statements in our product label are limited as the result of our single-arm, open-label study. **These limitations have a significant impact on our ability to market Andexxa and establish it as the standard of care**, as pharmaceutical companies are generally prohibited from making product claims not set forth in their product labels. These limitations can also increase resistance to utilization by hospital formulary committees and may also negatively impact government pricing discussions in the EU and abroad. (¶¶311-12.)

This alternative treatment gave rise to further uncertainty about market acceptance and use of Andexxa, thereby creating further uncertainty about whether the product would be returned.

- c. Portola's admission that distributors had accumulated excess inventory by Q4 2019 reflecting weakness in market demand and heightening the risk of product returns. Indeed, one of the three factors the Company gave for

its disappointing revenue figures at the end of the Class Period was lower sales, “lower distributor purchases to manage inventory” in order “to keep their inventory levels at a constant level in the fourth quarter.” (*E.g.*, ¶¶294-95.) As the Company has admitted in its filings, it has “visibility into the inventory remaining in the distribution channel.” (*E.g.*, ¶¶218, 232.)

- d. The January 9, 2020 admission that it was being forced to incur a \$5 million gross-to-net adjustment “due to a return reserve for short-dated product” as well as additional reserves for future returns. (¶282.)
- e. CFO Dier’s admissions during the Jan. 9, 2020 Conference Call that the reserve addresses both “what’s been returned, it’s a little bit of catch-up for the year, and then you need to make an estimate of what you think may be returned based on what you’ve seen so far. ... And then moving forward, we’ll have our classic return reserve adjustment as part of our gross-to-net calculations,” constitutes an admission that (i) their prior reserves were inadequate because they had to “catch up” and (ii) their return to a “classic return reserve adjustment” shows that they had not engaged in quarterly reviews. (¶285.)
- f. Dier’s further admission during the Jan. 9, 2020 Conference Call that reserves had not been calculated on a normalized basis until then:

We do think this onetime adjustment takes in effect a little bit of what came back **during the year** and what may come back going forward with some short-dated products still outstanding. **But going forward, our reserves will be calculated into our gross to net on a more normalized basis.** (¶284.)

379. The fact that the Company lacked a relevant reasonable basis, including relevant historical evidence and other factual bases, with which to conclude that “it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur” thereby precluding upfront revenue recognition during the Class Period is *further* evidenced by what the Company’s the financial disclosures in the FY 2019 Form 10-K, which reveal two key facts:⁶⁷

- a. First, as **Exhibit 3** illustrates, total Andexxa *product returns for FY 2018 sales were significant*, as they totaled \$5.0 million, or 18% of total 2018 gross product sales of \$27.7 million.
- b. Second, actual results demonstrate that *the Company underestimated 2018 product returns by approximately \$2.4 million or 48%*. As **Exhibit 3** shows, the Company estimated a rate of return of 9.4% by recording a reserve provision of \$2.6 million on gross product revenues of \$27.65 million at the end of FY 2018. However, the FY 2019 Form 10-K illustrates that an additional \$2.4 million reserve adjustment taken in 2019 related to the reversal and return of product sold and recognized during 2018. Given this significant reversal of revenue, the actual rate of return for 2018 sales was 18%, nearly twice the originally estimated reserve provision. This means that, combined with the \$2.6 million provision recognized in FY 2018, the total returns related to 2018 sales appear to

⁶⁷ To be clear, Plaintiffs do not concede that the corrections and actual reserves that the Company was presumably required to take in its FY 2019 Form 10-K were adequate or sufficient.

total \$5.0 million, or 18% of total 2018 gross product sales of \$27.7 million.

- c. Third, **Exhibit 3** also reveals that the Company's underestimation of returns for product sold in 2018 resulted in a significant reversal of 2018 net revenue in 2019. As of December 31, 2018, the Company had a \$299,000 ending reserve to cover its estimated product returns associated with its 2018 sales to customers. However, this reserve was clearly insufficient. The Company had to record an additional provision (and a material reversal of revenue) of \$2,373,000 in 2019 to cover the additional return of product sold during 2018, beyond the \$299,000 reserve established on December 31, 2018.
- d. Thus, as it pertains to 2019, **Exhibit 3** reveals that the Company did not record sufficient reserves to account for the high risk factors facing it, including that (i) Andexxa was a new product with limited historical experience; (ii) the Company sold short-dated product with a liberal right of return; and (iii) there were issues of market acceptance given that Andexxa's price as compared to Kcentra frustrated Andexxa's use, where hospitals either declined to order the more expensive drug or put draconian restrictions on its usage. Inventories were building and the Company's admitted insight into the channel should have provided them with insights into the sell-through trends that were seemingly inconsistent with estimate assumptions.

380. These false and misleading statements regarding the Company's compliance with GAAP were both qualitatively and quantitatively material.

381. From a qualitative perspective, the fact that the Company failed to comply with GAAP and ASC 606 was material in several ways. First, revenue was a critical metric. The Company represented that sales and market acceptance of Andexxa were critical to the Company's operations and investor value. (¶¶96-99.) Second, analysts focused on these issues, posed questions about these issues, and based their recommendations and price targets on this information. (E.g., ¶¶227, 242, 253, 257, 272-74, 285, 303, 306-10.) Third, the market reacted to the January 9, 2020, January 10, 2020, and February 26, 2020 news that demand was not as strong as believed and that revenues were down. The price drops were significant and based on unusually high trading volume. (¶¶282-309.) Fourth, in connection with the Company's FY 2019 financials, its auditors, Ernst & Young, flagged Portola's accounting practices for product return reserves as a "Critical Audit Matter" (or "CAM"). (¶313.) The language of the relevant SEC order makes clear that a CAM, by definition, amounts to an admission that reserves were "material" to Portola's financial statements.⁶⁸

382. From a qualitative perspective, as noted above, the Company's upfront recognition of revenue violated GAAP. That is, the absence of a relevant reasonable basis, including relevant historical evidence and other factual basis, with which to conclude that "it [was] probable that a significant reversal in the amount of cumulative revenue recognized

⁶⁸ See *Public Company Accounting Oversight Board; Order Granting Approval of Proposed Rules on the Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion, and Departures From Unqualified Opinions and Other Reporting Circumstances, and Related Amendments to Auditing Standards*, SEC Release No. 34-81916, File No. PCAOB-2017-01, 82 Fed. Reg. 49886-01 (Oct. 27, 2017).

[would] not occur” precluded Portola from recognizing revenue upon delivery. As such, the Company’s net revenue figures for both 2018 and 2019 were recognized out of period.

b. Defendants Issued Materially False and Misleading Statements Regarding Portola’s Compliance with Its Internal Revenue Recognition Policy

383. As set forth above, each of the Company’s Financial Reports confirmed that the Company internal policy provided that it followed ASC 606 and further stated that the Company would report product revenues net of applicable reserves (including returns) in each quarter.

384. These statements regarding the Company’s internal policies were materially false and misleading because the Company *did not follow its own internal policy* to report net revenues (net of reserves for variable consideration), as required, in every quarter. These statements were materially false and misleading for the same reasons as set forth in ¶¶374-79 (falsity) and ¶¶380-82 (materiality), above, regarding the GAAP violations.

385. These statements were materially false and misleading for the additional reason that, in the Jan. 9, 2020 Conference Call, Dier effectively admitted that Portola had not properly netted out reserves in each quarter of 2019 by stating that they were making a one-time adjustment in Q4 2019 for revenue that was returned *during 2019*;

- a. “We do think this onetime adjustment takes in effect a little bit of what came back *during the year* and what may come back going forward with some short-dated products still outstanding. *But going forward, our reserves will be calculated into our gross to net on a more normalized basis.* And like I said, we’re already starting to shift the long-dated 36-month product. We started that in November. So we feel good about this one adjustment.” (¶284.)

- b. When asked by an analyst in the same conference call whether the “\$5 million reserve is for product that is short-dated, but has not yet been returned,” Dier responded that the reserve addresses “both” “what’s been returned, it’s a little bit of catch-up *for the year*, and then you need to make an estimate of what you think may be returned based on what you’ve seen so far. That’s just accounting for return reserves.... So we come up with a calculation. We feel good about the \$5 million, taking the \$5 million now. *And then moving forward, we’ll have our classic return reserve adjustment as part of our gross-to-net calculations....* I’ll just reiterate again, the longer-dated product has already stated selling as of November, and that’s 36 months.” (¶285.)

c. Having Failed to Comply with GAAP, Defendants’ Net Revenue Figures were Materially False and Misleading

386. As set forth above, Portola reported net revenue figures and other financial figures based on the net revenue figures. These include the following statements:

- a. the Mar. 1, 2019 Press Release announcing fourth quarter Andexxa net revenues of \$14 million (¶225);
- b. Garland’s statement at the Mar. 1, 2019 Conference Call touting that “[t]his is our third consecutive quarter of strong revenues for Andexxa and reflects solid demand” (¶226);
- c. Garland’s statement at the Mar. 1, 2019 Conference Call touting that “I’m very pleased to report Q4 2018 net revenues of \$14 million” (¶226);
- d. Dier’s statement at the Mar. 1, 2019 Conference Call that “total revenues were \$15.3 million for the fourth quarter and \$40.1 million for the full

year 2018. Total revenues for the quarter included \$1.2 million in license and collaboration revenue” (§226);

- e. Dier’s statement at the Mar. 1, 2019 Conference Call that “net sales of Andexxa grew to \$14 million, a more-than-80% increase over the previous quarter and our third consecutive quarter of strong Andexxa revenues. This brings the 2018 revenues of Andexxa to \$24 million” (§226);
- f. the FY 2018 Form 10-K reported net product revenues of \$24.1 million (§235);
- g. the May 8, 2019 Press Release reporting total net revenues of \$22.2 million for Q1 2019, as compared to \$6.6 million for the first quarter of 2018, and total net revenues of \$20.3 from Andexxa sales (§238);
- h. the May 8, 2019 Conference Call where Garland, Dier, and Koenig reported Q1 2019 Andexxa net revenue of \$20.3 million and Garland reported total net revenue of \$22.2 million (§239);
- i. Dier’s May 8, 2019 Conference Call statement that Portola “had a strong first quarter with Andexxa revenues growing 45% of its fourth quarter and expenses in line with our guidance for the full year” (§239);
- l. the Q1 2019 Form 10-Q reported net revenue of \$20.3 million for Q1 2019 Andexxa sales (§247);
- j. Garland’s statement at the June 11, 2019 Goldman Sachs Healthcare Conference Call that “[w]e’ve now had 4 quarters of very solid revenue, the most recent of which was \$20.3 million net” (§252);

- k. the Aug. 7, 2019 Press Release announcing that “Andexxa[®] Net Product Revenues Grow to \$27.1 Million ... [t]otal revenues for the second quarter of 2019 were \$28.4 million, compared with \$4 million for the second quarter of 2018” (¶254);
- l. Koenig’s Aug. 7, 2019 Conference Call statement that there was “continued strength and demand for Andexxa. In fact, 74% of our sales in the quarter came from reorders, reflecting real pull through and increasing use in patients” (¶255);
- m. Garland’s Aug. 7, 2019 Conference Call statement that “our team’s exceptional execution on the launch of Andexxa is driving continued revenue growth. For the second quarter, net product revenues for Andexxa were \$27.1 million, marking our fifth consecutive quarter of strong revenue” (¶256);
- n. Dier’s Aug. 7, 2020 Conference Call statement that “[t]otal revenues were \$28.4 million for the second quarter driven by \$27.1 million in net revenues of Andexxa” (¶255);
- o. the Q2 2019 Form 10-Q reporting Q2 2019 net revenue of \$27.1 million (¶261);
- p. the Registration Statement, including the Prospectus Supplement, incorporating by reference the following documents that contained materially false and misleading net revenue figures: (a) the FY 2018 Form 10-K; (b) Q1 2019 Form 10-Q; and (c) Q2 2019 Form 10-Q (¶265);

- q. Garland's statements at the Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call about \$27.1 million in net revenues for Andexxa (§268);
- r. the Nov. 5, 2019 Press Release reporting total net global revenue of \$36.8 million, compared to \$14.2 million for the third quarter of 2018, and that the total global net revenue included \$35.7 million in net product revenue from sales of Andexxa/Ondexxya (§269);
- s. the Nov. 5, 2019 Conference Call statement by Koenig that "[e]xisting accounts continued to show strong pull-through, with 76% of sales in the quarter coming from utilization or reorders compared to 74% in the previous quarter" and "[t]his is an important metric because it reflects demand and significant pull-through in the hospitals where Andexxa is being used to treat patients" (§272);
- t. Garland's Nov. 5, 2019 Conference Call statement that "[i]n the third quarter, net product revenue for Andexxa were \$35.7 million. This includes \$33 million in net product sales for Andexxa in the United States and \$2.7 million in net product sales of Ondexxya in our wave 1 countries in Europe" (§271);
- u. Garland's Nov. 5, 2019 Conference Call statement that "[w]e also hit an exciting revenue milestone in the third quarter surpassing \$100 million in cumulative net sales since our launch in May of 2018" (§271);
- v. Koenig's Nov. 5, 2019 Conference Call statement that "[t]hese initial revenues of \$2.7 million reflect demand since the majority of sales to date

are direct to hospitals, unlike the U.S., where we distribute via wholesalers. All of this underscores the unmet need and demand in Europe for Andexxa” (¶272);

- w. Dier’s Nov. 5, 2019 Conference Call statement that “[t]otal revenues were \$36.8 million for the third quarter driven by \$35.7 million in global net revenues of Andexxa” (¶272); and
- x. the Q3 2019 Form 10-Q reporting (i) \$32.95 million for Andexxa net product revenue for the Q3 2019; and (ii) \$80.3 million in net revenue for Andexxa for the nine-months ending September 30, 2019 (¶276).

387. In reporting these revenues, net of reserves, Defendants provided reassurance to investors that these revenues were reliable and in conformity with GAAP and Portola’s internal policies.

388. Each of these reported revenue and related financial figures were materially false and misleading because the Company failed to comply with ASC 606 when it recognized revenue up front despite its inability to reasonably conclude that a significant reversal in the amount of revenue would not occur for the same reasons as set forth in ¶¶374-79 (falsity) and ¶¶380-82 (materiality), above, regarding the GAAP violations. *See also* Regulation S-X (17 C.F.R. § 210.4-01(a)(1)) (states financial statements filed with the SEC which are not prepared in compliance with GAAP are presumed to be misleading or inaccurate, despite footnote or other disclosure).

d. The Company's Internal Control Over Financial Reporting Failed to Prevent or Detect Portola's Violation of ASC 606 and Rendered Defendants Garland's and Dier's SOX Certifications Materially False and Misleading.

389. As set forth in ¶¶236, 249, 264, 279, above, Garland and Dier attested to SOX Certifications in connection with each of the Financial Reports issued during the Class Period, including assurances that no material weaknesses existed in Portola's effective internal control over financial reporting. Moreover, there were no qualification or limitation in any of these SOX Certifications contained in the 2019 Form 10-Qs indicating that the FY 2018 Form 10-K could no longer be relied upon. As such, the direction to read the 2019 Form 10-Qs in conjunction with the FY 2018 Form 10-K constituted a continuing affirmation of those certifications.

390. Each of these SOX Certifications (including the representation that the Company's financial statements fairly present the Company's financial condition) were materially false and misleading for the same reasons as set forth in ¶¶374-79 (falsity) and ¶¶380-82 (materiality), above, regarding the GAAP violations. For example, contrary to the Company's disclosures and assertions regarding the effectiveness of its internal controls, a material weakness in Portola's internal control over financial reporting existed during the Class Period. Specifically, the absence of effective controls to prevent or detect Portola's failure to comply with GAAP during the Class Period was a material weakness in internal controls. Accordingly, management's assurances regarding the effectiveness of the Company's Internal Control Over Financial Reporting, including the existence of no material weaknesses, were false and misleading.

B. Additional Allegations of Scienter

391. In addition to the detailed allegations above supporting scienter (including, but not limited to, those regarding the CWs descriptions of Defendants' knowledge of the true facts,

as detailed in the following paragraphs—*e.g.*, ¶¶103(e), 103(f), 103(g), 108, 115, 124, 130, 153-56, 168, 176, 180, 194, 198, 206), four key facts further support a strong inference of scienter as to the Company and each of the Officer Defendants

1. The Nature and Significance of the Problems with Andexxa, Which is the Company’s Core Business, Further Support Scienter

392. Andexxa was of crucial importance to the Company. It accounted for virtually all of the Company’s sales and was the Company’s only viable product after Bevyxxa’s mid-2018 catastrophic launch failure. It would be absurd to suggest that Officer Defendants and other senior executives (including Vice President of Sales Randy St. Laurent) were not intimately familiar with the status of and changes to key demand and utilization metrics, sales information and updates (including new hospital adds), and the reorder rate that was publicized by them regularly during analyst calls.

393. At the outset of the Class Period, on January 8, 2019, Defendant Garland articulated his focus on the core business and operations of Portola and its single viable product, Andexxa: on the January 8, 2019 Conference Call with analysts, Defendant Garland stated, “Cash is our fuel on this journey. We take it very seriously. It’s what is going to take to get us from this side to the other side of the river or the pond, and we’re being very judicious with how we spend our money.” With that statement, Defendant Garland was commenting on the Company’s burn rate of \$326 million in the previous year and the need to be careful and vigilant with expenses. Where Garland and his executive team (including Officer Defendants) were focused on the fact that cash was tight and were monitoring expenses and expenditures very carefully, they were also of course aware of how the Company’s single product was performing as it was brought to market. It is absurd to suggest otherwise.

394. Portola tracked sales and utilization through CRM software by Salesforce, and also used an excel spreadsheet to track additional information. That information was readily available to those in the Company whose position mandated that they have access to this information, and certainly Officer Defendants as well as their direct reports (which would include VP of Sales Randy St. Laurent) had access. CW6 explained that all management had access to it and, based on his/her experience in the industry, they “absolutely” tracked sales number daily, if not hourly.

395. In line with that, Garland expressly touted the data at his disposal and the Company’s sole focus on Andexxa. At the June 11, 2019 Goldman Sachs Global Healthcare Conference Call, Garland represented that the Company “track[s] the number of accounts that have ordered [Andexxa] at least once” and touted that there was “enough data to feel very confident in both the short- and the long-term trajectory of Andexxa.” As precursor to a question to Garland, an analyst made the following statement about Company vision: “So for investors who are maybe new to the story, *it seems it’s Andexxa, Andexxa, Andexxa.*” Garland’s response confirmed that the Company’s focus was solely on Andexxa: “*Right now, as you just said, we’re focused on Andexxa. And I think it’s important we stay focused on Andexxa* because we’ve got to get people confident we can execute and confident that we’ve got an asset that is going to be of great value.”

396. After announcing disappointing and unexpected sales results for FY 2019 on February 26, 2020, the Company reiterated its sole focus on Andexxa, reorganizing internally and finally discontinuing its hibernated Bevyxxa product’s connection to 10 hospitals, which was scaled back to that level after its catastrophic launch failure. During an analyst conference call on February 26, 2020, Garland explained: “*[W]e are laser focused on driving near-term*

revenue growth [for Andexxa]. To support this strategy, we have taken three important steps to realign attention and resource allocation towards expanding the Andexxa customer base, driving utilization and increasing market share.”

397. Given the extreme importance of Andexxa to the Company, the Officer Defendants’ access to reports and information about the problems with Andexxa’s commercialization process, their representations that their statements were based on data, and Garland’s statements about business focuses with regard to its sole product, the Officer Defendants knew or were deliberately reckless in ignoring the true facts that rendered the statements false and misleading when made.

2. Statements About Defendants’ Knowledge of Demand and Utilization Issues in Light of Andexxa’s Exorbitant Cost Further Support Scienter

398. The Officer Defendants’ statements as well as those by multiple CWs offer further support for scienter of Garland and the Officer Defendants, demonstrating knowledge about demand, utility, and cost as a barrier to sales.

399. The Officer Defendants closely monitored all aspects of Andexxa’s commercialization, were directly involved in the day-to-day operations of the Company at the highest levels, and were privy to confidential proprietary information concerning Andexxa. For example,

- ***Portola Queried Hospitals Concerning the Bleeds that Andexxa Treated.***
“But as we query multiple hospitals, we do see uses in other situations, GI patients with severe signs of shock or other critical bleeds. So we’re happy that it’s starting with the intracranial hemorrhages but then expanding to other labeled uses as well, as we expect.” (Jeet Mahal, Jan. 8, 2019 Conference Call.)
- ***Portola Talked to Hospitals about Utilization.***
“I do know that when we spoke to customers about Q4 utilization, ...” (Garland, Jan. 8, 2019 Conference Call.)

“What we are seeing, as we’ve looked at a cohort of our institutions, large important institutions that came on earlier at [ESP] and actually what we’re seeing is increased usage over time or deepening usage over time. ***There’s nothing that we’re seeing today*** that makes us concerned about a lack of pull-through or a plateauing of our utilization.” (Garland, Aug. 7, 2019 Conference Call.)

- ***Portola Tracked Hospital Purchases.*** “We also track internally the number of hospitals who’ve made their first purchase, the number of hospitals who’ve made their second, the number of hospitals that have made their third and more purchases. And we’re seeing steady increases week-on-week, month-on-month in those metrics.” (Garland, Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call.)
- ***Portola Chart Audits.*** “We do conduct a regular chart audit where we go out and pull records from patients who have been given Andexxa in the hospital. And what we’re seeing actually is broad utilization. We’re not seeing it niched to just intracranial hemorrhage.” (Garland, Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call.)⁶⁹
- ***Portola Mined Electronic Records from Hospitals.*** “[W]e mine electronic medical records from hospitals to look at patients who are discharged that were—had as a primary diagnosis a Factor Xa-related bleed. We take that data and we mirror it with the IMS prescription data for Eliquis and Xarelto to find just those patients that were discharged on a Xa-related—that had a Xa-related bleed as their primary diagnosis.” (Garland, June 11, 2019 Goldman Sachs Global Healthcare Conference.)
- ***Portola Tracked Andexxa Shipped to Hospitals from Distributors.*** “So we certainly have visibility into the data that goes from our distributors to our hospitals. ***We get that data on a relatively regular basis.***” (Garland, Mar. 1, 2019 Conference Call.)
- ***Garland Had Access To Critical Data.*** Garland highlighted the data at his and the Company’s disposal. At the June 11, 2019 Goldman Sachs Global Healthcare Conference Call, Garland represented that the Company “track[s] the number of accounts that have ordered [Andexxa] at least once” and touted that there was “enough data to feel very confident in both the short- and the long-term trajectory of Andexxa.” (Garland, June 11, 2019 Goldman Sachs Global Healthcare Conference.)

⁶⁹ See also Garland, Mar. 1, 2019 Conference Call (“[Portola uses] chart pulls to see if the actual – when the product ultimately gets used.... [W]e have is visibility into the hospital in terms of its use”).

400. Multiple CWs stated that Andexxa's high cost was a barrier to sales (which directly impacted demand and utilization) that was discussed regularly at Portola business meetings, both telephonically and in person. (*E.g.*, ¶¶103(c), 103(d), 103(e), 103(f), 103(g), 103(i), 106, 108, 119, 124, 126-28, 131, 138-41, 154-56, 198.)

401. Multiple CWs state that they raised the issue with their managers or regional managers. (*E.g.*, ¶¶103(g), 111, 140.)

402. Multiple salesperson CWs also discuss regularly held national sales calls and regional and national sales meetings in San Francisco. (*E.g.*, ¶¶103(e), 127, 140-41, 155, 198.) Cost as a barrier to sales was discussed regularly on these calls. And not only did VP of Sales Randy St. Laurent participated in these calls and meetings, but so too did Defendant Garland (and potentially other executive officers). For example,

- a. CW5 reported on national sales calls as well as national sales meetings held in San Francisco organized by the Vice President of Sales, Randy St. Laurent. Garland spoke on some calls and national meetings. CW5 said that upper management understood that cost was impacting sales and causing restrictions to be put in place. During calls, cost as the cause of slow sales and the implementation of restrictions was "always" discussed. When Garland addressed the issue, which he did both on calls and at meetings, he would articulate value of the drug over the issue with cost.
- b. CW12 stated that during "many town hall meetings," slow Andexxa sales was discussed as was the high price of the drug, which was said to be hindering sales. CW12 stated that Defendant Garland "danced around" those issues and did not address them directly.

- c. CW12 also reported that sales personnel did not feel like they were getting support from the “executive team” regarding the price of Andexxa and the difficulty selling it at that price, suggesting that the executive team knew but did not act.

403. Sales CWs 1, 5, and 6 stated that they are confident that Portola and its management knew about demand and utilization issues and Andexxa costs’ impact on them.

- a. CW1 said that Portola management “100%” knew that high cost versus benefit is why hospitals don’t use Andexxa and that the few hospitals that carry Andexxa place restrictions on its use, and that they used internal sales reporting programs to track this information. CW1 explained that sales reps are required to enter certain information into the system such as the name of the hospital, when the hospital was contacted, whether and when the P&T Committee is meeting about Andexxa, and, if Andexxa was purchased, what restrictions the hospital placed on prescribing Andexxa. CW1 said that Portola management knew that Andexxa is not widely used even by hospitals that carry it.
- b. CW6 similarly explained that management tracked sales information through CRM software provided by Salesforce. CW6 said that all management had access to it and, based on his/her experience in the industry, they “absolutely” tracked sales number daily, if not hourly.
- c. CW5 said that, from his/her perspective, the Portola sales force frequently advised management that the cost of the drug was hindering sales. According to CW5, the response from management was that the price was

not going to be reduced. To the extent management refers to management other than the Officer Defendants, it is inconceivable, given the frequency of the discussions and responses, that such a decision or response could be made without consulting informed Officer Defendants.

404. Similarly, hospital CWs stated that they are confident that Portola and its management knew about demand and utilization issues and Andexxa costs' impact on them.

- a. CW7 said that s/he believes Portola is aware of how hospitals are using Andexxa. According to CW7, s/he has told the Portola sales reps covering the system what restrictions the hospital system put in place on Andexxa.
- b. CW8 said Portola was aware that hospitals were restricting the use of Andexxa. CW8 said that in March 2020, during the virtual conference of the American College of Cardiology, s/he told the Portola representatives that the hospital system would continue to restrict Andexxa use and would not authorize it use for other types of indications such as GI bleeding.
- c. CW9 said that s/he knows that his/her team communicated the cost issue directly to officials at Portola. CW9 said that it was his/her opinion that Portola knows that the issue with Andexxa is cost, and not efficacy.
- d. CW11 believes that Portola knew that the cost of Andexxa was the reason the drug was not put on the hospital's formulary.
- e. CW13 reports pressing his/her hospital's Portola sales representative to lower the price of Andexxa, and that sales representative said that he/she would do what he/she could.

405. The direct knowledge of demand and utilization issues by Defendant Garland and his immediate subordinates supports that the Officer Defendants knew or were deliberately reckless in ignoring the true facts that rendered the statements false and misleading when made.

3. The Defendants Consummated the August 2019 Offering to Exploit the Artificial Inflation in the Company's Common Stock

406. Because of the substantial costs to manufacture and launch Andexxa along with other research and development projects, Portola had a significant cash burn even with Andexxa sales rolling in. The Defendants' false and misleading statements concerning the commercialization of Andexxa enabled Portola to artificially inflate the price of its shares of common stock for its August 2019 Offering. Consequently, Defendants were motivated to continue to misrepresent the sales and demand for Andexxa in order to keep Portola's stock price artificially inflated and to generate sufficient funds in the August 2019 Offering.

4. The Defendants Were Motivated to Inflate Andexxa Sales to Access the \$62.5 Million Second Tranche of the Secured Term Loan

407. In an effort to continue to fund its commercial launch of Andexxa, the Company announced on March 1, 2019 that it had entered into a \$125 million credit agreement with HealthCare Royalty Partners and its Affiliates ("HCR") and Athyrium Opportunities III Acquisition LP ("Athyrium") in February 2019 (the Secured Term Loan). However, HCR and Athyrium agreed to provide only one-half of the funds (or \$62.5 million) to Portola unless Andexxa net sales as reported pursuant to GAAP reached at least \$50 million by the end of the third quarter of 2019.

408. The loan under the credit agreement contained significant restrictions which impacted Portola's ability to operate its business because (i) it was secured by substantially all the Company's assets; (ii) required the Company to maintain \$31.3 million in cash (and \$50 million, if the Company drew down the second \$62.5 million tranche); (iii) limited or restricted

the Company from incurring additional debt; and (iv) limited its ability to make certain investments and acquisitions or engage in new lines of business.⁷⁰

409. The second tranche of \$62.5 million was to be available as of November 15, 2019 only if (i) the Company had received all regulatory approval from EMA for Ondexxya, and (ii) Andexxa's consolidated net sales for the three fiscal-quarter periods ending September 30, 2019 were at least \$50 million. If the Company did not achieve both these milestones, it would not receive the remaining \$62.5 million.⁷¹

410. On November 21, 2019, the Company announced that it had met the necessary \$50 million in Andexxa net sales requirement (having exceeded Andexxa net product revenues in the nine months ended September 30, 2019) and had drawn down the entire \$62.5 million available from the second tranche.⁷²

411. Since the Company's access to the \$62.5 million second tranche of the Secured Term Loan was essential to the Portola's survival, senior management was motivated to inflate Andexxa net sales as much as possible in the first three quarters of 2019 to meet the milestone. The Company did this by recognizing revenue in violation of ASC 606.

⁷⁰ FY 2018 Form 10-K, at 20, F-49, F-50.

⁷¹ *Id.*

⁷² Form 8-K, filed with the SEC on Nov. 21, 2019.

5. Defendants' Insider Trading is not Relevant to Their Scienter Because They were Motivated by Efforts to Sell The Company, Not by Short-Term Stock Sales

412. During the Class Period, several of the Officer and Director Defendants collectively sold millions of dollars of Portola stock.⁷³ However, the fact that their sales *may* not be deemed highly suspicious in amount or timing as compared to the pre-Class Period is irrelevant here and does not indicate that Defendants were not motivated to mislead the market.

413. Here, Defendants were motivated to find a suitable acquiror for the Company in order to reap both the financial benefits that they would personally receive in an acquisition and the expected bump up on the stock price upon news of an acquisition, which would support the retention of shares.

414. Although the Acquisition occurred three months after the end of the Class Period, Defendants' efforts to find such a suitor commenced long before the end of the Class Period. Indeed, as CW12 reported, s/he and many others believed that Garland's motivation during the Class Period was to position the Company to sell. And, indeed, the Merger Documents state and demonstrate that the groundwork for this Merger had begun long before the end of the Class Period.

415. The Merger Documents reveal that Portola had reached out to Alexion in Q2 2019 and Q3 2019 to discuss a potential strategic partnership and that they had a series of meetings discussing potential licensing, partnering, research and development, and other collaborative and strategic acquisition transactions including a potential strategic partnership

⁷³ Notably, because he was new to the Company, Garland's shares were not fully vested during the Class Period. Portola, Garland's Statements of Changes in Beneficial Ownership (Form 4s) (Oct. 31, 2018, Feb. 4, 2019, Nov. 4, 2019, Feb. 4, 2020, Feb. 26, 2020).

for a European Union (“EU”) license of Andexxa (marketed as Ondexxya in the EU).⁷⁴

Further, according to the Merger Documents, while those discussions with Portola temporarily ended in September 2019, they resumed in mid-November 2019 and early December 2019 by and among Dr. Aradhana Sarin (“Sarin”), the CFO of Alexion, and Defendant Dier in her capacity as the CFO and Chief Business Officer of Portola. Both Defendant Garland and Alexion CEO Dr. Ludwig Hantson (“Hantson”) joined in those discussions at that time as well.⁷⁵ The Merger Documents further reveal that, without specifying a transaction price, Dr. Sarin sent Garland a letter on December 13, 2019 requesting access to due diligence materials in order to inform a potential bid for Portola. The closing price on December 13, 2019 was \$26.31.⁷⁶

416. The Merger Documents further disclose that, on February 27, 2020, the last day of the Class Period and the day that the stock price fell again after the revelations regarding the demand for and utilization of Andexxa, Hantson and Sarin communicated with Garland and Dier that Alexion was interested in acquiring Portola for \$18.00 per share. Those discussions continued through the months leading up to the May 5, 2020 Merger announcement.⁷⁷ The timing of these price discussions is highly suspicious and supports an inference that, during their Merger negotiations, Portola was required to make certain disclosures to correct the stock price.

⁷⁴ Portola, Solicitation/Recommendation Statement (Schedule 14D-9) (May 27, 2020) (“May 27, 2020 Schedule 14D-9”), at 15-17.

⁷⁵ *Id.*

⁷⁶ *Id.* at 16.

⁷⁷ *Id.* at 17-23.

417. Portola’s Officer Defendants indeed benefited from the Merger in at least two ways as revealed in its post-Class Period May 27, 2020 Schedule 14D-9.⁷⁸

418. First, as part of the Executive Severance Benefits Agreements included in the Merger, the executive officers received a continuation of their base salary and bonus/equity awards: “We have entered into an Executive Severance Benefits Agreement with each of our executive officers that contains severance provisions providing for continuation of base salary and continuation of group health benefits for a specified period of time, and, in certain cases, a bonus payment and equity award vesting acceleration benefits, upon termination of the executive officer’s employment by the Company without ‘cause’ ... or resignation by the executive officer for ‘good reason.’”⁷⁹

419. Second, beyond simply, *inter alia*, the continued salary and bonus payments, the Officer Defendants enjoyed other benefits in the form of “Golden Parachute Compensation” consisting of severance/bonus payments and the acceleration of vesting of Portola Options, Portola Restricted Units (“RSUs”) and Portola performance-based restricted stock units (“PSUs”).⁸⁰

420. Portola’s May 27, 2020 Schedule 14D-9 reveals the following significant “Golden Parachute Compensation” estimated to be received by Portola’s executive officers, including the officer Defendants, relating to the merger:⁸¹

⁷⁸ *Id.* at 4 (“Portola’s directors and executive officers may have interests in the Offer, the Merger and the other Transactions that are different from, or in addition to, the interests of Portola’s stockholders generally.”).

⁷⁹ *Id.* at 9.

⁸⁰ *Id.* at 12-14.

⁸¹ *Id.* at 13.

Defendant	Cash	Equity	Perquisites/ Benefits	Tax Reimbursement	Total
Garland	\$2,548,156	\$6,069,057	\$79,389	\$3,125,221	\$11,811,823
Dier	\$1,079,066	\$1,945,550	\$27,626	—	\$3,052,242
Koenig	\$924,562	\$1,956,800	\$27,626	\$1,144,666	\$4,053,654

The left-hand column in the foregoing table describing “Cash” includes a “double-trigger” amount consisting of (a) “the cash severance payments under each executive’s severance benefits agreement,” and (b) “a prorated bonus with respect to 2020.”⁸² The column describing “Equity” refers to vesting acceleration that each of those defendants will receive with respect to his or her “**Accelerated In-The-Money Options** pursuant to the terms of the Merger Agreement.”⁸³

421. Further, the value of Defendants’ options, RSUs and PSUs increased significantly because they were scheduled to receive actual cash for the options, RSUs and PSUs by reason of vesting *on an accelerated basis* due to the Merger. The following chart shows the total value and accelerated value which Defendants received for their options upon the Merger.⁸⁴

Defendant	Shares Underlying Vested In- the-Money Options	Value of Vested In-the- Money Options	Shares Underlying Accelerated In-the- Money Options	Value of Accelerated In-the- Money Options	Total Value
Garland	12,500	\$65,125	287,500	\$1,497,875	\$1,563,000
Dier	4,062	\$21,163	93,438	\$486,812	\$507,975
Koenig	4,062	\$21,163	93,438	\$486,812	\$507,975
Wolff	10,520	\$115,720	0		\$115,720

⁸² *Id.* at 13, note (2).

⁸³ *Id.* at 13, note (3).

⁸⁴ *Id.* at 7.

422. Certain other consideration to be received by the Officer Defendants noted below consisted of a right to convert shares underlying the Portola Rollover RSUs and PSUs into shares of Alexion at the accelerated values referenced below:⁸⁵

Defendant	Shares Underlying Portola Rollover RSUs	Acceleration Value of Portola Rollover RSUs	Shares Underlying Portola PSUs	Acceleration Value of Portola PSUs	Total Acceleration Value
Garland	153,399	\$2,761,182	100,000	\$1,800,000	\$4,561,182
Dier	32,291	\$581,238	48,750	\$877,500	\$1,458,738
Koenig	32,916	\$592,488	48,750	\$877,500	\$1,469,988

423. Moreover, as expected, the Acquisition price of \$18 per share was a bump up from the Company's \$7.76 stock price close the day before the Merger Announcement.⁸⁶ The following is a chart that shows the bump up on the value of the stock that they owned.⁸⁷

Defendants	Shares Held Prior to Merger⁸⁸	Value On Day Before Merger Acquisition⁸⁹	Value of Shares Based on the Merger Price	Difference	% Premium
Garland	24,529	\$190,345	\$441,522	\$251,177	231. 96%
Dier	39,563	\$307,009	\$712,134	\$405,125	231. 96%
Koenig	5,075	\$39,382	\$91,350	\$51,968	231. 96%
Renton	16,020	\$124,315	\$288,360	\$164,044	231. 96%
Bird	527,172	\$4,090,855	\$9,489,096	\$5,398,242	231. 96%

⁸⁵ *Id.* at 8.

⁸⁶ This bumped-up \$18 per share price was far lower than the trading prices between the Class Period start and the last trading date before the first partial disclosure (May 4, 2020), which ranged from \$22.18 to \$37.26. Had there been no fraud, the Class Members would not have paid as much as they did for their shares purchased at inflated prices during the Class Period but would have still benefited from any mark-up resulting from the Acquisition.

⁸⁷ The shares listed herein exclude Portola options, RSUs, and PSUs.

⁸⁸ May 27, 2020 Schedule 14D-9 at 5.

⁸⁹ This is calculated by multiplying the number of shares held by Portola's stock price at the market close on May 4, 2020, the date before the Merger Announcement, *i.e.*, \$7.76.

Defendants	Shares Held Prior to Merger⁸⁸	Value On Day Before Merger Acquisition⁸⁹	Value of Shares Based on the Merger Price	Difference	% Premium
Brege	13,194	\$102,385	\$237,492	\$135,107	231. 96%
Fenton	13,194	\$102,385	\$237,492	\$135,107	231. 96%
Johnson	13,194	\$102,385	\$237,492	\$135,107	231. 96%
Stump	13,194	\$102,385	\$237,492	\$135,107	231. 96%
Wolff	17,960	\$139,370	\$323,280	\$183,911	231. 96%

C. Loss Causation

424. At all relevant times, Defendants issued materially false and misleading statements regarding (i) the commercialization of Andexxa, including that demand was strong and growing; (ii) the Company's compliance with GAAP; (iii) the Company's compliance with its own internal revenue recognition policies; (iv) attestations contained in Garland and Dier's SOX Certifications; and (v) the Company's revenue results. As a result of these false and misleading statements, Portola's common stock price was artificially inflated during the Class Period. Lead Plaintiff and other Class members purchased Portola's common stock at those artificially inflated prices.

425. The true facts started to be revealed through a series of partial disclosures at the end of the Class Period, as detailed in Section V.H., above, which allegations are incorporated herein. As the true facts started to be revealed, the prior artificial inflation came out of its stock price and the Company's common stock declined.

426. In response to the first partial disclosure after the market close on January 9, 2020 revealing, among other things, that Andexxa demand was flat due to a decline in utilization and that preliminary results that were significantly below consensus estimates, the Company's share price plummeted by \$9.98, or approximately 40%, to close at \$14.76 per

share on January 10, 2020 on unusually heavy trading volume. Meanwhile, the Nasdaq Composite Index and the Nasdaq Biotech Index decreased 0.4% and 0.3% respectively, on January 10, 2020.

427. This news was a major resetting of expectations with regard to Andexxa. Analysts reacted negatively to the January 9, 2020 news and Oppenheimer, Cowen, Credit Suisse and Morgan Stanley downgraded their ratings and/or lowered their price targets for Portola stock on January 9 and January 10, 2020.

428. Portola's stock price continued to fall on the next trading day, closing down 6.2% at \$13.84 on January 13, 2020 on heavy trading. Meanwhile, the Nasdaq Composite Index increased 1.0% and the Nasdaq Biotech Index fell 1.2% on January 13, 2020.

429. After the close of market on February 26, 2020, Portola announced its financial results for the fourth quarter and full year 2019 in its Feb. 26, 2020 Press Release and held its Feb. 26, 2020 Conference Call that, among other things, revealed in more detail the serious problems with customers' adoption of the Andexxa drug, raised further concerns after the Company's pre-announcement of financial results the previous month and reported greater losses than average analysts' estimates. Portola also announced expected new hospital adds of 350 hospitals that were below expectations; that, as one analyst wrote, "impl[ied] a deceleration from the 425 hospitals added in 2019." Analyst reports after that call primarily focused on what the announcement meant for Andexxa.

430. On this February 26, 2020 news, the Company's share price fell \$2.35 to close at \$10.17 per share on February 27, 2020, an approximately 19% decline, on heavy trading volume. Meanwhile, the Nasdaq Composite Index and the Nasdaq Biotech Index decreased 4.61% and 4.13% respectively, on February 27, 2020.

431. Moreover, while analysts had lowered their expectations for Andexxa after the Company's January 2020 pre-announcement, management's refusal to provide any additional insight on Andexxa utilization trends during the Feb. 26, 2020 Conference Call was cause for even further alarm over the drug's true prospects. As a result, several analysts expressed further concern regarding their limited visibility going forward and further cut their target price down from their January 2020 cut.

432. The economic loss suffered by Lead Plaintiff and the other Class members was a direct result of the Defendants' fraud and material false and misleading statements to artificially inflate the prices of Portola's common stock and the subsequent decline in the value of Portola's common stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

433. The timing and magnitude of the common stock price decline coupled with the market reactions negate any inference that the losses suffered by Lead Plaintiff and other members of the Class were caused solely by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct. Accordingly, these false and misleading statements directly or proximately caused Lead Plaintiff and other Class members to suffer damages.

D. Presumption of Reliance

434. Lead Plaintiff is entitled to a presumption of reliance under the fraud-on-the-market doctrine. At all times, the market for the Company's securities was an efficient market that promptly digested current information related to the Company from all publicly available sources and reflected such information in the prices of the Company's securities. Throughout the Class Period:

- a. Portola common stock was actively traded on the NASDAQ;
- b. the market price of Portola's common stock reacted promptly to the determination of public information regarding the Company;
- c. the Company's stock was followed by financial analysts, including those cited in this complaint;
- d. the average weekly trading volume for Portola stock during the Class Period was over 3.5 million shares;
- e. as a regulated issuer, Portola filed with the SEC periodic public reports during the Class Period;
- f. Portola regularly communicated with public investors via established market communication mechanisms; and
- g. during the Class Period, the Company had over 78 million shares outstanding. Also, the Company's market capitalization reached as high as \$2.4 billion during the Class Period.

435. Throughout the Class Period, the Company was consistently followed by the market, including securities analysts. The market relies upon the Company's financial results and management to accurately present the Company's financial results. During this period, Portola and the Officer Defendants continued to pump materially false and misleading information into the marketplace regarding the Company. This information was promptly reviewed and analyzed by analysts and institutional investors, and assimilated into the price of the Company's securities.

436. As a result of the misconduct alleged herein (including Defendants' false and misleading statements and omissions), the market for Portola's common stock was artificially

inflated. Under such circumstances, the presumption of reliance available under the “fraud-on-the-market” theory applies. Thus, Class members are presumed to have indirectly relied upon the misrepresentations and omissions for which Defendants are each responsible.

437. Lead Plaintiff and other Class members justifiably relied on the integrity of the market price for the Company’s securities and were substantially damaged as a direct and proximate result of their purchases of Portola’s common stock at artificially inflated prices and the subsequent decline in the price of those securities when the truth was disclosed.

438. Lead Plaintiff and the other Class members are also entitled to a presumption of reliance under *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the claims asserted in this complaint against Defendants are predicated upon omissions of material fact for which there was a duty to disclose. Because this action involves Defendants’ failure to disclose material adverse information regarding the utilization and adoption of Andexxa—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of hospital customers’ and other institutions’ utilization and adoption of Andexxa, that requirement is satisfied here

439. Had Lead Plaintiff and other members of the Class known of the material adverse information not disclosed by Defendants or been aware of the truth behind Defendants’ material misstatements, they would not have purchased Portola’s common stock at artificially inflated prices.

E. Exchange Act Counts

**1. Count One – Violations of Section 10(b) and Rule 10b-5
(Against Portola and the Officer Defendants)**

440. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

441. Throughout the Class Period, the Company and the Officer Defendants, directly or indirectly, by the use of means or instrumentalities of interstate commerce, the United States mails, interstate telephone communications, and a national securities exchange, made untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, and engaged in acts, practices, and a course of business which operated as a fraud and deceit upon Lead Plaintiff and the other members of the Class in connection with their purchases of the common stock of Portola during the Class Period, all in violation of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5 promulgated thereunder.

442. The Company and Officer Defendants, as the most senior officers of Portola during the Class Period, are liable as direct participants in all of the wrongs complained of through the date they left the Company.

443. As detailed above, Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and disclose such facts even though such facts were available to them.

444. Lead Plaintiff and other members of the Class relied upon Defendants' statements and/or on the integrity of the market in purchasing shares of Portola's common stock during the Class Period.

445. As a direct and proximate cause of the wrongful conduct described herein, Lead Plaintiff and the Class suffered damages in connection with their purchases of Portola's common stock at artificially inflated prices during the Class Period. Had Lead Plaintiff and the other members of the Class known of the material adverse information not disclosed by Defendants, or been aware of the truth behind Defendants' materially false and misleading statements, they would not have purchased Portola's common stock at artificially inflated prices during the Class Period.

446. In addition to the duties of full disclosure imposed on the Officer Defendants, as a result of their responsibility for the Company's financial statements and making affirmative statements and reports to the investing public, the Officer Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC, including accurate and truthful information with respect to the Company's business operations, growth, and financial condition, so that the market price of the Company's securities would be based on truthful, complete, and accurate information.

447. By virtue of the foregoing, Defendants violated 10(b) of the Exchange Act and SEC Rule 10b-5(b) promulgated thereunder and are liable to Lead Plaintiff and the Class members who have been damaged as a result of such violations.

2. Count Two – Violations of Section 20(a) of the Exchange Act (Against the Officer Defendants)

448. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

449. The Officer Defendants acted as control persons of Portola within the meaning of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a). By virtue of their high-level positions,

agency, and their ownership and contractual rights, participation in and/or awareness of Portola's operations, and/or intimate knowledge of the false financial statements filed by Portola with the SEC and disseminated to the investing public, the Officer Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of Portola, including the content and dissemination of the various statements that Lead Plaintiff contends are false and misleading. The Officer Defendants were provided with or had unlimited access to copies of Portola's reports, press releases, public filings, and other statements alleged by Lead Plaintiff to have been misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

450. In particular, each Officer Defendant had direct and supervisory involvement in the day-to-day operations of Portola and therefore is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations alleged and exercised that power.

451. As a direct and proximate result of the Officer Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchases of Portola's common stock during the Class Period.

452. As set forth above, Portola and the Officer Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint.

453. By reason of the conduct of Portola alleged in this complaint, and by virtue of their positions as control persons, the Officer Defendants are liable pursuant to Section 20(a) of the Exchange Act.

VII. SECURITIES ACT VIOLATIONS

A. Summary of Offering

454. Lead Plaintiff and named representative, Oklahoma Firefighters, bring claims arising under the Securities Act, 15 U.S.C. §§ 77k, 77l(a)(2), and 77o, against all Defendants. In this action, and, as explained above, the “Class” consists of all persons and entities who purchased or otherwise acquired Portola common stock between January 8, 2019 and February 26, 2020, inclusive and were damaged as a result. The Securities Act claims asserted herein are brought on behalf of only those Class members who purchased or otherwise acquired shares of Portola common stock pursuant and/or traceable to the Company’s August 2019 Offering. The Securities Act claims solely allege strict liability and negligence causes of action, and do not sound in fraud. Accordingly, for the purpose of these Securities Act claims, Lead Plaintiff expressly excludes and disclaims any allegation that could be construed as alleging fraud, intentional misconduct, or deliberately reckless misconduct. In addition, this disclaimer expressly excludes all allegations above contained in (a) paragraphs 1, 2, 3, 5, 9, 10, 11, 12, 13, 16, 17, 19, 20, 22, 23, 24, 25, 26, 28, 29, 30, 31, 32, 45, 82, 83, 84, 102, 103, 104, 108, 109, 110, 115, 116, 124, 130, 140, 141, 153, 154, 155, 156, 160, 168, 176, 180, 194, 196, 198, 200, 201, 280, 297, 298, 304; (b) all paragraphs in Section VI(A)(2), except for paragraphs 374-76(e), 376(g), 378, 379, 380-82; and (c) all paragraphs in Sections VI(A)(1), VI(B), VI(C), VI(D), and VI(E) in their entireties.

455. On August 7, 2019, the Company filed the Registration Statement with the SEC. The Registration Statement became effective on August 7, 2019. On August 12, 2019, Portola filed a Preliminary Prospectus Supplement on Form 424(b)(5) with the SEC, which preliminarily announced a public offering. On August 14, 2019, the Company filed a Prospectus Supplement on Form 424(b)(5) with the SEC. In the Registration Statement and

Prospectus, Portola incorporated by reference the following Company documents: (a) the FY 2018 Form 10-K; (b) Q1 2019 Form 10-Q; and (c) Q2 2019 Form 10-Q. As described at ¶265, above, these are the Offering Materials.

456. On August 14, 2019, shares of Portola common stock issued in connection with the Offering commenced regular public trading. The Offering closed on August 16, 2019.

457. The Underwriter Defendants acted as the underwriters and book-running managers in connection with the Offering. The Underwriter Defendants were granted a 30-day option to purchase an additional 1,205,357 shares of common stock at the offering price to cover over-allotments in connection with the Offering.

458. The Underwriter Defendants received a fee of \$14.2 million and exercised their over-allotment option in full. In total, the Offering raised gross proceeds of over \$258 million for the Company.

459. The proceeds raised in the Offering were allegedly to be used:

[T]o fund the commercial launch of Andexxa in the United States and Ondexxa in the European Union, support on-going manufacturing and clinical trial costs required to satisfy post-marketing commitments required by the FDA and EMA, as well as clinical trial costs for proposed label expansion studies for Andexxa/Ondexxa and advancing our product candidate, cerdulatinib; and ... for working capital, capital expenditures and other general corporate purposes, which may include the acquisition or licensing of other products, businesses or technologies.

B. The Materially Untrue and Misleading Statements in the Offering Materials

460. The Underwriting Agreement, included as Exhibit 1.1 to the Registration Statement and the Company's Current Report filed on Form 8-K with the SEC on August 14, 2019, falsely represented that "the Registration Statement and the Prospectus comply ... in all material respects with the Securities Act and the applicable rules and regulations of the [SEC] thereunder," and "did not contain ... any untrue statement of a material fact or omit to state a

material fact required to be stated therein or necessary to make the statements therein not misleading.”

461. Contrary to this representation and, as set forth below, the Offering Materials contain numerous untrue statements of material fact, and omit material facts required to be stated therein or omit to state material facts necessary to make the statements therein not misleading, concerning the demand for Andexxa and the Company’s revenues. Moreover, these material untrue statements and omissions constitute violations of Item 303 of Regulation S-K (17 C.F.R. § 229.303(a)(3)(ii)), which requires that the Offering Materials disclose “any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations.” and Item 105 of Regulation S-K (17 C.F.R. § 229.105), which requires that the Offering documents disclose a “discussion of the most significant factors that make the offering speculative or risky.”

1. Untrue and Misleading Statements Concerning New Hospital Additions and Reorder Rates

462. In the Prospectus, Portola touted two non-GAAP metrics: hospital adds and reorder rate.

Andexxa is tracking with the most successful among 45 other acute care hospital drugs launched in the past 30 years based on average quarterly sales for the first four full quarters of launch. In addition, in the second quarter of 2019, ***Andexxa had a reorder rate of 54% with 74% of Andexxa revenues from reorders for the quarter.*** In the same period ***we added 125 additional hospitals for a total of over 400 hospitals*** that have ordered Andexxa since launch.

463. The Company portrayed these metrics as strong indicators that Andexxa was being well-received by hospitals, that Andexxa was receiving strong demand, and that the full commercial launch was a success. These statements were untrue. Moreover, even if some are argued to be literally true – and they are not – the context and manner of their presentation make

them untrue and misleading statements that do not have the ability to inform, but instead mislead, investors.

464. These metrics were misleading because (i) the new hospital additions included hospitals that did not intend to use Andexxa, but stock it only for liability purposes only, or so heavily restricted Andexxa use that it was unlikely that the Andexxa stock would ever be used, and (ii) the “reorder rate” was not a valid indicator of demand and pull-through in hospitals particularly because it concealed the magnitude of reorders and included all hospitals in its calculation whether they had been stocking Andexxa for several quarters or were added just recently. It is further misleading because what contributes to “reorder rates” is neither defined nor known. For example, does “reorder rate” include exchanges of returned expired or short-shelf-life doses for longer-life doses? Does it include the return of original 100 mg FDA-approved Andexxa for newly-FDA-approved 200 mg Andexxa? These inputs, if included, would be extraordinarily misleading.

465. The truth that “new hospitals added” and “reorder rates” were not reliable metrics to show demand for Andexxa is evidenced by the following statements by former employees of Portola:

- a. statements by CW1 that (i) hospitals had difficulty justifying the high cost of Andexxa and that they could rely on other treatments that they had been using for years without spending as much; (ii) the data concerning the effectiveness of Andexxa did not justify the cost versus the benefit; (iii) some hospitals were carrying Andexxa as a “CYA” and did not intend to use it; and (iv) because of price, a hospital covered by CW1 had very

restrictive use protocols in place limiting Andexxa's use to life-threatening intracranial bleeds (§§106-07);

- b. statements by CW3 that (i) sales of Andexxa were stagnant throughout his/her time at Portola selling the drug; (ii) Andexxa's price was problematic, "[i]t was a struggle for [him/her] from day one to sell Andexxa," and "the hospital pharmacists were terrified of [Andexxa] and not from a clinical point[, but] strictly from a cost point"; (iii) small, rural hospitals that CW3 called on believed that Andexxa was priced "way too aggressively" and many could not afford it; (iv) a hospital with 100 beds or less would have to make a choice between purchasing Andexxa and hiring a staff member because of the high cost; and (v) Kcentra, another anticoagulant reversal drug, was a cheaper alternative to Andexxa for many hospitals; and (vi) a professor of pharmacology and clinical specialist paid to speak on the benefits of Andexxa by Portola at a June 2018 Hospital Pharmacy Society conference that was attended by 55 hospital pharmacists stated that he would nonetheless use Kcentra over Andexxa because of its cost (*e.g.*, §§118-20, 122-23);
- c. statements by CW4 that (i) sales of Andexxa were slow throughout the time that s/he worked at Portola and sold Andexxa; (ii) hospital pharmacists were shocked at the price difference between Kcentra and Andexxa, and that cost was the reason for slow sales; (iii) s/he believed that hospitals were initially worried about being sued if a patient died following a severe bleed and the particular hospital did not carry Andexxa,

but an article written by three pharmacists in 2019 provided hospital pharmacy directors with information to push back on ordering Andexxa; (iv) many hospitals used the publication of the article to further bolster their position that Andexxa was too expensive to carry when a cheaper alternative such as Kcentra was available; and (v) the high cost of Andexxa put a strain on pharmacy budgets (*e.g.*, ¶¶126, 127, 129, 131);

- d. statements by CW5 that (i) from his/her perspective, the biggest issues Portola had concerning Andexxa usage was the cost of the drug combined with the off-label use of Kcentra; (ii) Andexxa was very expensive and sales stayed at a consistent level until there was a decline; (iii) through his/her own observations and communications with other sales reps, the rate of sales of Andexxa were not increasing during 2019 throughout the Class Period; (iv) pharmacies made the purchasing decisions, and they told doctors who wanted Andexxa that the drug was not available or that its use was restricted and that Kcentra was the only available treatment on the formulary; (v) while sales numbers were steady, some hospitals stocked up but did little reordering; (vi) s/he heard from other sales reps that beginning in the second half of 2019, there was an increase in the volume of returns, which s/he described as a large amount of returns of Andexxa; (vii) he/she believes that hospitals made a cost versus utilization analysis and determined that it was too costly to stock more than 3 to 5 boxes of Andexxa or to reorder additional boxes given that the indications were so limited; and (viii) insurance coverage does not affect a hospital

pharmacy department's decision about whether to purchase Andexxa because third-party reimbursement tends to go back to the general hospital accounts and generally does not get refunded to the pharmacy department's budget (*e.g.*, ¶¶137-39, 142-43, 146); and

- e. statements by CW6 that (i) many hospitals refused to add Andexxa to their formularies because of its high price, telling him/her that they have learned to manage bleeding with these patients and that they have strategies that have been working so they wouldn't purchase at the current price; (ii) "[a]s soon as the customers saw the price, they said that they have lived without it for five or six years and that they could live without it longer"; (iii) two Level I large bed trauma center hospitals in his/her district pushed back on the pricing of Andexxa and placed restrictions on who could use the drug; (iv) 90% of his/her customer calls responded with a "flat-out 'no;'" and (v) Portola was "absolutely" struggling to sell Andexxa in the period leading up to its August 2019 Offering (*e.g.*, ¶¶148-51, 157); and
- f. statements by CW12 that (i) working in the San Francisco headquarters, s/he was aware that the sales of Andexxa were not going well via "lunchroom" conversation with people in the Sales Division; and (ii) s/he believes that, in the Spring of 2019, sales had "come down," based on lunchroom conversations with sales staff, who were asking why sales were not going well (¶¶197, 199).

466. The truth that “new hospitals added” and “reorder rates” were not reliable metrics to show demand for Andexxa is further evidenced by the following statements by customers or potential customers who were marketed Andexxa by Portola:

- a. statements by CW7 that (i) s/he presented Andexxa to the P&T Committee, and it was felt that the data presented in the clinical trial was “flimsy;” (ii) nonetheless, the hospital felt that it was irresponsible to not carry the drug while prescribing Xarelto or Eliquis; it restricted use to only life-threatening intercranial bleeding for patients being treated with Xarelto or Eliquis, which s/he understands is consistent with how hospitals throughout the country are utilizing Andexxa; (iii) the hospital system only stocks one high dose and one low dose of Andexxa because the usage is so limited, where the system only authorizes Andexxa’s use for intercranial bleeding, which is normally accompanied by a stroke; (iv) in his/her hospital system, restrictions were based on effectiveness and not price; (v) it is not that Andexxa is ineffective, but it is only appropriate for certain indications and is not a “miracle drug;” (vi) the data on the use of Kcentra was as effective in many of the same situations as Andexxa; and (vii) it is his/her understanding that his/her hospital’s practices are consistent with how hospitals throughout the country are utilizing Andexxa (*e.g.*, ¶¶162-64, 166-67);
- b. statements by CW8 that (i) his/her hospital system has Andexxa on its formulary but restricts its usage to only life-threatening events involving intercranial bleeding; (ii) the decision to restrict Andexxa’s use is based on

the cost versus benefit and the data presented in Portola's clinical trials;

(iii) treatments such as Kcentra and Feiba have been used in the past and have been shown to be effective for less cost; (iv) throughout the entire hospital system, Andexxa has been used less than half a dozen times;

(v) the data supporting use of Andexxa for GI bleeding was not enough to support its use for that type of bleed (vi) Portola conducted an additional study of Andexxa, the results of which were presented at the American Society of Hospital Pharmacists convention in December 2019 in Las Vegas, Nevada and, in his/her opinion, the study was weak and still not convincing enough to change the Andexxa restrictions; and (vii) s/he believes that most hospitals have similar restrictions on Andexxa (*e.g.*, ¶¶171, 173-75);

- c. statements by CW9 that (i) his/her team determined that the cost of Andexxa was too high when the benefits are compared with other medications, including PCC treatments such as Kcentra and Feiba, which were effective for significantly less cost; (ii) most hospitals in his/her hospital's peer group have made the same determination concerning Andexxa—that it is too costly when compared with other treatments;
- (iii) it is possible that, by carrying Andexxa, a hospital pharmacy may be unable to hire a technician or otherwise fill a vacant position; and
- (iv) Andexxa is a drug that would come out of the hospital pharmacy's budget (and third-party reimbursements do not affect the cost to the pharmacy department) (*e.g.*, ¶¶179, 181-83);

- d. statements by CW10 that (i) his/her hospital determined that the cost of Andexxa was too prohibitive to carry and that there was no justification for Andexxa's pricing when they could try other things; (ii) if they had a patient that was critical and needed Andexxa, then the patient should be immediately transferred by ambulance to a larger hospital within the area that carried Andexxa; and (iii) the hospital's CCO said that other drugs that were cheaper than Andexxa, such as Kcentra, could be used (*e.g.*, ¶¶188-89);
- e. statements by CW11 that (i) the high cost is why Andexxa was kept off the hospital's formulary, where the hospital had a cheaper, reasonable alternative in Feiba; (ii) both a 2018 P&T Committee review of Andexxa as well as a review by medical staff informed and supported that position; and (iii) s/he believes that many other hospitals in his/her state made a similar choice as his/her facility to not add Andexxa to their formularies (*e.g.*, ¶¶191-93) and
- f. statements by CW13 that (i) his/her hospital limits the use of Andexxa to intracranial bleeds due to cost; (ii) his/her hospital carries it for fear of liability; and (iii) that s/he believes other hospitals in his/her region that accept critical patients from his/her hospital do not carry Andexxa due to cost (*e.g.*, ¶¶203-05).

467. The truth that "new hospitals added" and "reorder rates" were not reliable metrics to show demand for Andexxa is further evidenced by an admission made by Garland during the Sept. 10, 2019 Morgan Stanley Global Healthcare Conference Call when he stated that the

Company could not rely on it and shifted to a new metric percentage of revenue from reorders, and by a response that Garland gave to a question during the Nov. 5, 2019 Conference Call when he was asked where he had seen the reorder rate trending and what the Company expected for the rate going forward and he avoided substantively answering the past trend question and declined to provide “*any sort of* forward-looking guidance.”

- a. **[Garland]:** The reorder rate, we’ve talked about before, it was 55%, which was stable quarter-on-quarter, is heavily influenced by when a hospital comes online. And remember, we added 125 hospitals in the second quarter. Many of those were later in the quarter. And as a result, they are in the denominator, but they haven’t been around long enough to contribute to the numerator. ***So that had an impact on the reorder rate, which is why we gave it a new metric, which was that roughly 3/4 of our business, or 74% of our business, came from reorders.*** So what we’re seeing consistently is that the drug is getting utilized. (¶268.)
- b. **[Analyst]:** I’m just wondering if you could start to give ... some kind of on a comparison or, if it’s high level even about the current utilization at some of those hospitals that have been online for at least a year maybe even over a year versus maybe some that have come online in the past six month....

[Garland]: [N]ow that we’ve got a couple of years under—or a year under our belt how does the utilization look[?] We aren’t giving any detailed information around utilization per hospital per month. ***What we have seen is that, that utilization per hospital per month stays—has been staying consistent in 2019.*** (¶273.)

468. The truth that “new hospitals added” and “reorder rates” were not reliable metrics is further evidenced by the following:

- a. the Company’s ultimate admissions on January 9, 2020 that the Portola encountered “[f]lat quarter over quarter demand due to a decrease in utilization, primarily in tier 1 accounts” and that in certain of these accounts, hospital pharmacies curtailed use of Andexxa following drug utilization reviews in an effort to manage pharmacy budgets” (¶282);

- b. the Company's admissions on January 14, 2020 that Andexxa sales had fallen because of "lower distributor purchases to manage inventory" in order "to keep their inventory levels at a constant level in the fourth quarter" (§§295-96);
- c. the Company's acknowledgement on February 26, 2020 that the Company was "laser focused on driving near-term revenue growth [for Andexxa]" and was taking three important steps to "realign attention and resource allocation towards expanding the Andexxa customer base, driving utilization and increasing market share," including the discontinuation of the limited remaining Bevyxxa operations (§301); and
- d. the Company's admission in its FY 2019 Form 10-K filed on February 28, 2020 that it knew since Andexxa was approved by the FDA in early 2018 via the Accelerated Approval Program that the ANDEXXA-4 study proffered and relied up had "inherent limitations" that could impact the viability of Andexxa, where, for example, the Company was having significant difficulties competing with the off-label use of 4F-PCCs and other coagulation factors given a lack of comparative data and that hospital formulary committees were resistant to utilizing Andexxa because the Company lacked a clinical trial data comparing it to treatments used before Andexxa's FDA approval (§§311-12).

469. These untrue statements were material because a reasonable investor would have relied on these metrics because Portola viewed these as reliable indicators of demand for Andexxa and showed that the commercialization of Andexxa was a success. Further, analysts

noted in reports throughout the Class Period that demand and utilization of Andexxa were factors driving the commercial success of the Company:

- “[W]e continue to see notable upside in Portola shares as the commercial expansion of Andexxa into additional hospitals drives revenue growth and label expansions into emergency surgery and enoxaparin reversal increase the total market opportunity.” (William Blair, Apr. 4, 2019.)
- “The next few quarters will be critical to see how the initial demand translates into orders and sales and the likelihood of the product being able to achieve the \$1.34Bn in peak global sales that we currently forecast.” (Credit Suisse, May 8, 2019.)
- “[M]anagement remains very encouraged by the launch and believes it is progressing better than expected based on analogues of other hospital launches from the past 30 years. The message remains that the relatively slow uptake should not be unexpected at the outset of a hospital launch, the US demand for Andexxa is strong and growing.” (Credit Suisse, June 27, 2019.)
- “We are encouraged by the continued growth of Andexxa, particularly with 74% of sales in the quarter coming from hospitals reordering Andexxa. In addition, management commentary continues to be positive, highlighting the increased utilization trends with current accounts, recent increase in CMS NTAP reimbursement level (to 65% from 50%), access to the Veterans Administration health system, and first sales in Europe. We believe there is continued long[-]term momentum for Andexxa beyond the addition of new accounts over the next several quarters, including strong growth of the factor Xa class, label expansion to include urgent surgery and enoxaparin, and continued guidance recommendations including the recent Joint Commission updates.” (William Blair, Aug. 8, 2019.)
- “Andexxa is now available in roughly 550 hospitals in the United States, including another 125 new hospitals added in the quarter, and 76% of sales were from reorders as opposed to initial stocking (compared to 74% in the second quarter). We believe the continued uptake of Andexxa has been encouraging in both the United States and Europe, and continue to see a long-term opportunity for Andexxa through increasing penetration into a rapidly growing market.” (William Blair, Nov. 6, 2019.)

470. The significant stock drops on January 10, 2020, January 13, 2020, and February 27, 2020, which revealed the weak demand and utilization of Andexxa as well as the visibility for demand going forward further demonstrate the materiality of these untrue and misleading statements. Further, analyst reports reacting to the news pointed specifically to issues

of demand and utilization as factors both explaining the Company results and stock drops demonstrates the materiality of the untrue and misleading statements (*e.g.*, ¶¶287-93, 306-10).

2. Untrue and Misleading Statements Regarding Portola's Compliance with GAAP, Portola's Compliance with Its Own Revenue Recognition Policy, Portola's Net Revenue Figures, and The SOX Certifications

471. The Company's FY 2018 Form 10-K, the Q1 2019 Form 10-Q, and the Q2 2019 Form 10-Q, incorporated into the Registration Statement, included untrue and misleading statements regarding (i) the Company's compliance with GAAP; (ii) the Company's net revenue figures; (iii) the Company's compliance with its own internal Revenue Recognition Policy; and (iv) Garland's and Dier's SOX Certifications.

472. These statements were untrue and misleading because the Company lacked a reasonable basis, including sufficient relevant historical evidence and other factual bases, to recognize revenue under ASC 606. More specifically, Defendants *lacked sufficient relevant historical evidence and other facts to conclude "that it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur,"* which was required for the Company to report revenue. As such, Portola was precluded from recognizing revenue upon sell-in, *i.e.*, upon shipment to its distributors, rendering materially untrue or misleading its (a) statements of compliance with GAAP and Portola's Revenue Recognition Policy, (b) reported revenue figures in the FY 2019 Form 10-K, Q1 2019 Form 10-Q and the Q2 2019 Form 10Q; and (c) SOX Certifications regarding, among other things, the Company's internal controls.

473. The fact that Portola lacked a reasonable basis, including relevant historical evidence and other factual bases, to conclude that "it [was] probable that a significant reversal in the amount of cumulative revenue recognized [would] not occur" is evidenced by the following:

- a. the fact that the Company did not have *any* sufficient relevant historical sales and return data with which to conclude that it was “probable” that there would not be a significant reversal in the amount of revenue due to returns, as discussed in ¶¶374-75, above:
- b. the *confluence* of facts, *all of which existed contemporaneously with the Company’s decision to recognize the revenue*, demonstrating that Portola ignored serious concerns regarding the length of uncertainty of whether and when Andexxa sales might be returned due to expiring dates, price concerns, restrictions on use, lack of utilization, and lack of market acceptance, as discussed in ¶¶376(a)-376(e), 376(g) above. Because of these facts, the Company should not have recognized the revenue it reported in its Financial Reports. Since product sales for Andexxa did not begin until May 2018, sales of Andexxa short-dated product (*i.e.*, expiration periods of between 6 to 12 months) during 2018 and most of 2019 would not in most cases have reached its expiration in time to generate sufficient historical data to calculate any remotely reliable rate and amount of forecasted product returns for either 2018 or 2019. Compounding this difficulty in estimating was the existence of Kcentra, a competing and far less expensive substitute product;
- c. the Company’s admissions at the end of the Class Period that (i) there had been a decrease in utilization; (ii) Portola lacked visibility into utilization trends; and (iii) Portola added a new risk disclosure conceding that the fact that Andexxa lacked clinical data comparing its efficacy with that of

widely used 4F-PCCs like Kcentra which had affected its ability to compete with a common standard of care preceding Andexxa and conceding that Portola knew that Kcentra and other 4F-PCCs were still being used over Andexxa (consistent with the CW reports);

(iv) distributors had amassed excess inventory by Q4 2019, which reduced sales; and (v) the Company incurred a \$5 million gross-to-net adjustment due to returns of short-dated product *during* 2019, *see* ¶378; and

- d. the fact that the Company understated reserves for returns by 48% in FY 2018 and that 18% of its 2018 sales were returned in 2018 and 2019, resulting in a significant reduction of revenue during 2018 and 2019, as discussed in ¶379.

474. These untrue and misleading statements were material from both a qualitative and quantitative perspective as discussed in ¶¶380-82, above.

C. The Securities Act Counts

1. Count One – Violations of Section 11 of the Securities Act (Against all Defendants, Except Koenig)

475. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein, with the exception of any allegation that could be construed as alleging fraud, recklessness, or intentional misconduct. In addition this disclaimer expressly excludes all allegations above contained in (a) paragraphs 1, 2, 3, 5, 9, 10, 11, 12, 13, 16, 17, 19, 20, 22, 23, 24, 25, 26, 28, 29, 30, 31, 32, 45, 82, 83, 84, 102, 103, 104, 108, 109, 110, 115, 116, 124, 130, 140, 141, 153, 154, 155, 156, 160, 168, 176, 180, 194, 196, 198, 200, 201, 280, 297, 298, 304; (b) all paragraphs in Section VI(A)(2), except for paragraphs 374-76(e), 376(g),

378, 379, 380-82; and (c) and all paragraphs in Sections VI(A)(1), VI(B), VI(C), VI(D), and VI(E) in their entireties.

476. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of all members of the Class who bought shares of Portola common stock pursuant and/or traceable to the Offering Materials, which includes the Registration Statement, against all Defendants (except Koenig). This Count is based solely on claims of strict liability and/or negligence under the Securities Act.

477. As set forth above, the Offering Materials contained untrue and/or misleading statements of material fact, omitted material facts which were necessary to make those statements not misleading, and omitted to state material facts required to be stated in it. The facts misstated and omitted would have been material to a reasonable person reviewing the Offering Materials.

478. Class members who purchased or otherwise acquired shares pursuant and/or traceable to the Offering Materials did not know, or in the exercise of reasonable diligence could not have known, of the untrue statements of material fact or omissions of material facts in the Offering Materials.

479. This Action was commenced less than one year from the time Class members discovered or reasonably could have discovered the facts upon which this cause of action is based. This Action commenced less than three years from the time that the securities upon which this cause of action is brought were bona fide offered to the public.

480. Class members who purchased or otherwise acquired shares pursuant and/or traceable to the Offering Materials have sustained damages and are entitled to damages pursuant to 15 U.S.C. § 77k(e).

481. Portola is the registrant for the Offering and, as issuer of the shares, it is strictly liable to Lead Plaintiff and to the members of the Class for materially untrue and/or misleading statements and omissions alleged herein.

482. None of the other Defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Offering Materials were accurate and complete in all material respects. Had they exercised reasonable care, they would have known of the material misstatements and omissions alleged in this Count.

483. Defendants Garland, Dier, and the Director Defendants signed or authorized the signing of the Registration Statement. By virtue of signing the Registration Statement, they issued, caused to be issued, and participated in the issuance of the Offering Materials, which contained untrue statements of material fact, omitted to state other facts necessary to make the statements not misleading, and omitted to state material facts required to be stated therein. The Underwriter Defendants acted as the underwriters of the Offering within the meaning of Section 11 of the Securities Act by selling and distributing the Portola common stock offered to the investing public and purchased or otherwise acquired by Lead Plaintiff and members of the Class.

484. For the foregoing reasons, all Defendants (except Koenig) violated Section 11 of the Securities Act and are strictly liable to Class members who purchased or otherwise acquired shares pursuant and/or traceable to the Offering Materials.

**2. Count Two – Violations of Section 12(a)(2) of the Securities Act
(Against Portola and the Underwriter Defendants)**

485. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein, with the exception of any allegation that could be construed as alleging

fraud, recklessness, or intentional misconduct. In addition this disclaimer expressly excludes all allegations above contained in (a) paragraphs 1, 2, 3, 5, 9, 10, 11, 12, 13, 16, 17, 19, 20, 22, 23, 24, 25, 26, 28, 29, 30, 31, 32, 45, 82, 83, 84, 102, 103, 104, 108, 109, 110, 115, 116, 124, 130, 140, 141, 153, 154, 155, 156, 160, 168, 176, 180, 194, 196, 198, 200, 201, 280, 297, 298, 304; (b) all paragraphs in Section VI(A)(2), except for paragraphs 374-76(e), 376(g), 378, 379, 380-82; and (c) all paragraphs in Sections VI(A)(1), VI(B), VI(C), VI(D), and VI(E) in their entireties.

486. This Count is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77l(a)(2), on behalf of all members of the Class who purchased or otherwise acquired Portola common stock pursuant to the Offering Materials, which includes the Prospectus, against Portola and the Underwriter Defendants. This Count is based solely on claims of strict liability and/or negligence under the Securities Act.

487. Portola and the Underwriter Defendants were sellers, offerors, or solicitors of purchasers of the shares offered pursuant to the Offering Materials.

488. By means of the Offering Materials (as well as instruments of transportation and communication in interstate commerce and the mails), the Defendants named in this Count, through the Offering, which was a public offering, solicited and sold Portola common stock to members of the Class.

489. As set forth above, the Offering Materials contained untrue and/or misleading statements of material fact, omitted material facts which were necessary to make those statements not misleading, and omitted to state material facts required to be stated in it. The facts misstated and omitted would have been material to a reasonable person reviewing the Offering Materials.

490. Class members who purchased or otherwise acquired shares pursuant to the Offering Materials did not know, or in the exercise of reasonable diligence could not have known, of the untrue statements of material fact or omissions of material facts in the Offering Materials.

491. This Action commenced less than one year elapsed from the time Class members discovered or reasonably could have discovered the facts upon which this cause of action is based. This Action commenced less than three years elapsed from the time that the securities upon which this cause of action is brought were sold to the public.

492. As the issuer of the registered securities, Portola is strictly liable for the untrue statements and omissions of material facts contained in the Offering Materials.

493. None of the Underwriter Defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Offering Materials were accurate and complete in all material respects. Had they exercised reasonable care, they would have known of the material misstatements and omissions alleged in this Count.

494. By reason of the foregoing, Portola and the Underwriter Defendants are liable for violations of Section 12(a)(2) of the Securities Act to Class members who purchased or otherwise acquired securities sold pursuant to the Offering Materials. These Class members also have the right to rescind and recover the consideration paid for these securities upon tender of their stock to the Underwriter Defendants, and to recover rescissory damages to the extent they have already sold the securities.

3. Count Three – Violations of Section 15 of the Securities Act (Against the Officer and Director Defendants)

495. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein, with the exception of any allegation that could be construed as alleging fraud, recklessness or intentional misconduct. In addition this disclaimer expressly excludes all allegations above contained in (a) paragraphs 1, 2, 3, 5, 9, 10, 11, 12, 13, 16, 17, 19, 20, 22, 23, 24, 25, 26, 28, 29, 30, 31, 32, 45, 82, 83, 84, 102, 103, 104, 108, 109, 110, 115, 116, 124, 130, 140, 141, 153, 154, 155, 156, 160, 168, 176, 180, 194, 196, 198, 200, 201, 280, 297, 298, 304; (b) all paragraphs in Section VI(A)(2), except for paragraphs 374-76(e), 376(g), 378, 379, 380-82; and (c) all paragraphs in Sections VI(A)(1), VI(B), VI(C), VI(D), and VI(E) in their entireties.

496. This Count is brought pursuant to Section 15 of the Securities Act, 15 U.S.C. § 77o, on behalf of all class members who bought shares of Portola common stock pursuant and/or traceable to the Offering Materials, which includes the Registration Statement and Prospectus, against the Officer and Director Defendants. This Count is based solely on claims of strict liability and/or negligence under the Securities Act.

497. At all relevant times, the Officer and Director Defendants were controlling persons of Portola within the meaning of Section 15 of the Securities Act. As set forth herein, by reason of their positions of control and authority as officers and/or directors of Portola, the Officer and Director Defendants had the power to directly or indirectly control or influence Portola to engage in the acts described herein, including by causing Portola to conduct the Offering pursuant to the Offering Materials, and exercised the same.

498. Specifically, the Officer Defendants each served as an executive officer of Portola prior to and at the time of the Offering. As such, at all relevant times the Officer Defendants

each participated in the operation and management of Portola, including participating in the preparation and dissemination of the Offering Materials, and/or otherwise participated in the process necessary to conduct the Offering. By virtue of their positions as officers of Portola, and their status as signatories of the Registration Statement, each of the Officer Defendants had the power to control, and did control, Portola in its conduct of the Offering, including controlling the contents of the Offering Materials, which contained materially untrue statements. As officers of a publicly owned company, the Officer Defendants had a duty to disseminate accurate and truthful information with respect to Portola's business operations, growth, and financial condition.

499. Similarly, each of the Director Defendants served as directors on Portola's Board at the time the Offering was conducted. As directors of a publicly owned company, the Director Defendants had a duty to disseminate accurate and truthful information with respect to the Portola's operations at the time of the Offering. Each Director Defendant signed the Registration Statement disseminated to the investing public and were Directors of the Company at the time the Offering was conducted. Thus, the Director Defendants controlled the contents and dissemination of the Offering Materials.

500. None of the Officer or Director Defendants conducted a reasonable investigation or possessed a reasonable basis for the belief that the statements contained in the Offering Materials were true, were without omissions of material fact, and were not misleading. By reason thereof, each of the Officer and Director Defendants is liable under Section 15 of the Securities Act, jointly and severally with, and to the same extent as the Company is liable under Sections 11 and 12(a)(2) of the Securities Act, to the Class members who purchased or otherwise acquired Portola common stock pursuant and/or traceable to the Offering Materials.

501. As a direct result of the aforementioned conduct, these Class members suffered damages in connection with their purchase of Portola common stock. This Action commenced less than one year elapsed from the time Class members discovered or reasonably could have discovered the facts upon which this cause of action is based. This Action commenced less than three years elapsed from the time that the securities upon which this cause of action is brought were bona fide offered or sold to the public.

VIII. CLASS ALLEGATIONS

502. Lead Plaintiff brings this action as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil procedure on behalf of a class consisting of all persons and entities who purchased or otherwise acquired Portola common stock during the Class Period, including shares sold in the August 2019 Offering, and were damaged as a result (the “Class”). Excluded from the Class are: (a) Defendants; (b) members of the immediate families of Defendants; (c) the subsidiaries and affiliates of Defendants; (d) any person who is an officer, director or controlling person Portola; (e) any entity in which any Defendant has a controlling interest; (f) Defendants’ directors’ and officers’ liability insurance carriers, and any affiliates or subsidiaries thereof; and (g) the legal representatives, heirs, successors, or assigns of any such excluded party.

503. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are thousands of members in the proposed Class. Indeed, as of February 20, 2020, Portola had 78,080,365 outstanding shares of common stock.

504. Members of the Class may be identified from records maintained by Portola or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice customarily used in securities class actions.

505. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class, including:

- a. whether the federal securities laws were violated by Defendants' respective acts as alleged herein;
- b. whether the statements made were materially false or misleading, or omitted material facts;
- c. whether Defendants acted knowingly or with deliberate recklessness in issuing false and misleading financial statements in violation of the Exchange Act claims;
- d. whether the Underwriter Defendants exercised due diligence;
- e. whether the prices of Portola's securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
- f. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

506. Lead Plaintiff's claims are typical of the claims of other members of the Class and the other members of the Class sustained damages arising out of Defendants' wrongful conduct in violation of federal law as alleged in this complaint.

507. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class actions and securities litigation. Lead Plaintiff has no interests antagonistic to, or in conflict with, those of the Class.

508. A class action is superior to other available methods for the fair and efficient adjudication of the controversy since joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by the individual Class members may be relatively small, the expense and burden of individual litigation makes it impracticable for the Class members individually to redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

509. Lead Plaintiff will rely, at least in part, on the presumption of reliance established by the fraud-on-the-market doctrine. All purchasers of Portola's securities during the Class Period suffered similar injuries, including injury through their purchase of the securities at artificially inflated prices. A presumption of reliance therefore applies.

IX. NO SAFE HARBOR

510. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false and misleading statements pleaded in this complaint. The statements alleged to be false and misleading all relate to historical or then-existing facts and conditions.

511. In addition, to the extent certain of the statements alleged to be false may be characterized as forward-looking, they were not adequately identified as "forward-looking statements" when made, and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

512. Alternatively, to the extent that the statutory safe harbor is intended to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because, at the time each of those forward-looking statements was made, the particular speaker had actual knowledge that the particular forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized and/or approved by an executive officer of Portola who knew that those statements were false, misleading, or omitted necessary information when they were made. In addition, to the extent any of the statements set forth above were accurate when made, they became inaccurate or misleading because of subsequent events, and Defendants failed to update those statements which later became inaccurate.

X. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for relief and judgment as follows:

- a. Determining that this action is a proper class action, certifying Lead Plaintiff as Class representative under Federal Rule of Civil Procedure 23, and appointing Lead Plaintiff's counsel as Class Counsel;
- b. Awarding compensatory and/or rescissory damages in favor of Lead Plaintiff and the other members of the Class against all Defendants for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre- and post-judgment interest thereon;
- c. Granting equitable and/or injunctive relief as permitted by law, equity and federal law;
- d. Awarding Lead Plaintiff and the Class their reasonable fees and expenses incurred in this action, including counsel fees and expert fees; and

- e. Awarding such other and further relief as the Court may deem just and proper.

XI. DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Lead Plaintiff hereby demands a trial by jury.

DATED: November 5, 2020

Respectfully submitted,

BERMAN TABACCO

By: /s/ Nicole Lavallee
Nicole Lavallee

Daniel E. Barenbaum
Jeffrey V. Rocha
44 Montgomery Street, Suite 650
San Francisco, CA 94104
Telephone: (415) 433-3200
Facsimile: (415) 433-6382
Email: nlavallee@bermantabacco.com
dbarenbaum@bermantabacco.com
jroacha@bermantabacco.com

-and-

Lindsey B. Silver
BERMAN TABACCO
One Liberty Square
Boston, MA 02109
Telephone: (617) 542-8300
Facsimile: (617) 542-1194
Email: lsilver@bermantabacco.com

*Counsel for Lead Plaintiff Alameda County
Employees' Retirement Association and
Lead Counsel for the Class*

David R. Kaplan (SBN 230144)
Brandon Marsh (SBN 268316)
SAXENA WHITE P.A.
12750 High Bluff Drive, Suite 475
San Diego, CA 92130
Telephone: (858) 997-0860
Facsimile: (858) 369-0096
Email: dkaplan@saxenawhite.com
bmarsh@saxenawhite.com

*Attorneys for Additional Plaintiff Oklahoma
Fire Fighters Retirement System*